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OCCUPATIONAL EXPOSURE TO 1, 2-DIBROMO-3-CHLOROPROPANE (DBCP)

Occupational Safety and Health Standards

[4510-26]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to 1,2-Dibromo-3-Chloropropane (DBCP)

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This standard is based on a determination by the Occupational Safety and Health Administration that the available scientific evidence establishes that employee exposure to DBCP presents a hazard of sterility and cancer. This standard replaces the emergency temporary standard (ETS) for exposure to DBCP (42 FR 45536 September 9, 1977), and limits employee exposure to DBCP to 1 part DBCP per billion parts of air (1 ppb) as an 8-hour time-weighted average concentration. The standard also prohibits eye and skin contact with DBCP. The standard provides for employee exposure monitoring, engineering controls and work practices, respirators, personal protective equipment and clothing, employee training, medical surveillance, regulated areas, hygiene practices and facilities, and record-keeping. The basis for this standard is OSHA's determination that human and animal data demonstrate that DBCP causes sterility and that animal data indicates that exposure to DBCP presents a cancer hazard to workers.

EFFECTIVE DATE: This new permanent standard is effective April 17, 1978. The provisions contained in the ETS are continued in effect until superseded by the new permanent standard.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This permanent occupational safety and health standard is issued pursuant to sections 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and Title 29, Code of Federal Regulations (CFR) Part 1911. It amends Part 1910 of 29 CFR by revising 29 CFR 1910.1044, to provide a permanent standard for the regulation of occupational exposure to DBCP. In order to assure that affected employers and employees will be informed of the existence of these provisions and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the new requirements, the effective date of the revision to § 1910.1044 will be April 17, 1978. To provide continued protection for employees until that date, the provisions currently contained in § 1910.1044 are promulgated pursuant to sections 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act as an occupational safety and health standard effective March 17, 1978. The revisions to § 1910.1044 will supersede the current provisions as of April 17, 1978. This standard applies to all employments in all industries covered by the Act, including "general industry", construction and maritime, excluding only agriculture. As discussed more fully below, only the labeling, training and emergency provisions of the standard apply to the handling of sealed, intact containers of DBCP.

I. Background

DBCP has been used as an agricultural nematocide since 1955. It is a dense yellow or amber liquid with a pungent odor at high temperatures. It has a low vapor pressure (0.8 mm Hg at 20° C) and is slightly soluble in water (1,000 ppm).

DBCP, a halogenated hydrocarbon, is produced primarily by the bromination of allyl chloride at room temperature, usually a vigorous reaction which requires cooling. DBCP is produced in the United States by Dow Chemical Company and Shell Oil Company. Mexico, Japan and Israel also manufacture DBCP and export DBCP to this country. About 12 million pounds of DBCP were consumed in 1972.

Following manufacture, DBCP is shipped to formulators who reprocess the chemical into products for consumer use. DBCP has been formulated into emulsifiable concentrates, liquid concentrates, powder, granules, and solid material. Formulating granular DBCP involves spraying liquid DBCP onto inert granules. The formulation of liquid and emulsified DBCP products usually involves the blending of technical grade DBCP with an emulsifier or solvent. The formulators may also distribute the technical grade product. About 80 formulators have labels registered with EPA for the approximately 160 products containing DBCP (42 FR 48026). The complete distribution chain generally includes the manufacture of technical grade DBCP, transportation to the formulator, formulation of DBCP-containing pesticides, distribution of DBCP-containing pesticides, and the agricultural consumption of DBCP pesticides. It is estimated that about 1,600 to 2,900 production employees in facilities manufacturing and formulating DBCP have been recently exposed to this chemical (exhibit 6, pp. 3-8).

Additionally, through the International Labor Organization's health hazard alert system OSHA has learned that, in addition to Japan, Mexico and Israel, the Netherlands, Finland and Sweden have also used DBCP. None of these nations was previously aware of the possible sterility effects of DBCP. All have suspended use of the substance, and Israel, Japan and the Netherlands have initiated further studies into the health effects of DBCP (exhibit 49).

II. History of Regulation

(1) Chronology of Events

In 1961, a research paper by Torkelson et al. recommended that occupational exposure to DBCP be controlled to less than 1 ppm in air (exhibit 4—56). This recommendation was based on observed reproductive effects in animals exposed to atmospheric concentrations of DBCP as low as 5 ppm. However, no national concensus standard of Federal standard for exposure to DBCP was developed prior to OSHA's emergency temporary standard discussed below.

In late July, 1977, preliminary results of semen analyses of 27 DBCP exposed employees at the Agricultural Chemical Division (a formulator of DBCP) of the Occidental Chemical Co. in Lathrop, Calif., indicated severely depressed sperm counts in eleven of these employees (exhibit 4-63). Based on these results, the Oil, Chemical and Atomic Workers (OCAW) requested on August 5, 1977, that the National Institute for Occupational Safety and Health (NIOSH) conduct a health hazard evaluation at this Occidental Chemical Co. plant. NIOSH contracted with Environmental Health Associates of Berkeley, Calif. to perform this evaluation, which later confirmed a high incidence of sterility and infertility at this plant.

Preliminary test results of employees at Dow Chemical Co.'s DBCP production facility in Magnolia, Ark., showed low sperm counts for several of these employees (exhibit 9, p. 54). On the basis of the results of these studies, Dow suspended production and sale of DBCP on August 12, 1977 (exhibit 9, p. 54). Shell Oil Co., the other major producer of DBCP in the United States, was not manufacturing DBCP at that time. Both Shell and Dow immediately requested the return of outstanding stocks of the substance (exhibit 4-60, 4-61).

In a telegram dated August 12, 1977, OSHA alerted approximately 80 man-

ufacturers and formulators to the potential hazard of worker exposure to DBCP (exhibit 4-56). On August 25, a guideline document detailing suggested work practices was forwarded to those same affected companies (exhibit 4-56).

On August 23, 1977, the Oil, Chemical and Atomic Workers International Union President, A. F. Grospiron, formally requested the Secretary of Labor to take immediate steps to prevent worker exposure to DBCP. Specifically OCAW requested that worker exposure be limited to one part DBCP per billion parts of air, and that a broad testing program to locate incidences of cancer and sterility among workers be established (exhibit 4-38).

(2) EMERGENCY TEMPORARY STANDARD

Based on a determination that the available data conclusively established that employee exposure to DBCP presented a grave danger of sterility as well as cancer, OSHA published an Emergency Temporary Standard (ETS) on September 9, 1977 (42 FR 45536) regulating DBCP exposure in the workplace. A correction document was published on September 16, 1977 (42 FR 46540). The emergency standard issued under sections 6(c) and 8(c) of the Act as 29 CFR 1910.1044, established an 8-hour time-weighted average (TWA) permissible exposure level of 10 parts DBCP per billion parts of air, with a permissible ceiling exposure level of 50 ppb as averaged over any 15 minute period in the workday. The ETS also established other requirements, including, for example, monitoring, methods of compliance, respiratory protection, medical surveillance and training.

Interested persons were invited to submit written data, views and arguments with respect to the issues raised by the ETS.

(3) THE SAN FRANCISCO INQUIRY

The California Department of Industrial Relations convened an inquiry to investigate the causes of the Occidental Chemical Co. DBCP incident, and to propose mechanisms to prevent any such occurrences in the future. The inquiry extended from October 12 through October 19, 1977. Participating were representatives of Occidential Chemical Co., Dow Chemical Co., Shell Oil Co., and the State of California as well as expert witnesses from the University of California at Berkeley. The transcripts of the inquiry and related exhibits were entered as exhibit 10 into the OSHA record for DBCP rulemaking.

(4) THE CINCINNATI CONFERENCE

A conference concerning DBCP was sponsored by NIOSH in Cincinnati, Ohio., on October 20 and 21, 1977. The purpose of the conference was to share information acquired by various groups concerning DBCP exposure. At this conference the findings of sterility at the Occidental Chemical Company were discussed, as well as the findings of Shell Oil Company and Dow Chemical Company at their DBCP manufacturing plants. Also, nationally recognized experts made presentations concerning DBCP-related issues such as semen analysis, mutagenicity, environmental monitoring and respiratory protection. The verbatim transcript of this conference was entered into the OSHA record as exhibit 9.

(5) THE PROPOSAL

In the November 1, 1977, issue of the FEDERAL REGISTER, OSHA published a comprehensive proposal for a permanent standard for occupational exposure to DBCP (42 FR 57266). The proposal called for an 8-hour TWA permissible exposure level of 1 ppb, with a ceiling of 10 ppb averaged over any 15 minute period. In addition, the proposal included a prohibition on skin exposure to the substance.

Unlike the ETS, the proposal required that the employer reduce employee exposures to or below the permissible exposure limit solely through engineering and work practice controls. Where these controls were not able to reduce exposures to within the permissible exposure limit, the proposal required that such controls be used to the greatest extent feasible and then be supplemented by the use of respirators.

The proposal allowed 30 days for interested parties to submit written comments, views and arguments, and announced that an informal public hearing for the submission of oral testimony would begin on December 13, 1977. Fourteen comments were received by OSHA. Twelve notices of intent to appear at the hearing were also received.

(6) THE HEARING

The OSHA rulemaking hearing (hereafter referred to as the hearing) was conducted from December 13 through December 15, 1977, before an Administrative Law Judge. The parties which were represented and presented oral testimony at the hearing were the Pesticide and Pollution Action Committee of Clemson University; South Carolina Peach Council; South Carolina Department of Agriculture; Industrial Union Department, AFL-CIO; Shell Oil Company; Oil, Chemical and Atomic Workers Union; California Department of Food and Agriculture; and California Department of Industrial Relations. All of these participants were given the opportunity to present testimony and to question other witnesses. Parties participating in the hearing were given until December 30, 1977, for the submission of new evidence, and until January 16, 1978, for the submission of post-hearing briefs and comments. Twenty-four post-hearing submissions were received.

(7) FINAL ENVIRONMENTAL IMPACT STATEMENT

In conjunction with the development of the proposed standard, OSHA prepared a draft environmental impact statement. The draft environmental impact statement was published in the FEDERAL REGISTER (42 FR 57266). On November 11, 1977, the Council on Environmental Quality published a notice of availability of the DBCP draft environmental impact statement (exhibit 7). In addition to the 45 day comment period specified in 29 CFR 1999.4 (g), the environmental impact of the proposed standard was also an issue at the DBCP hearing as provided by 29 CFR 1999.4 (h) and the notice of proposed rulemaking (42 FR 57266). A notice of availability of the final environmental impact statement for DBCP was published on March 3, 1978 by EPA (43 FR 8846).

(8) THE RECORD.

This permanent DBCP standard is based on a careful consideration of the entire record in this proceeding, including materials relied on in the emergency temporary standard, materials referenced in the proposal, and the record of the informal rulemaking hearing including the transcript, exhibits, and pre-hearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-061, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue, NW., Washington, D.C. 20210.

III. PERTINENT LEGAL AUTHORITY

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards. Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for ensuring the existence of safe and healthful workplaces. The Act provides that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employ-

ee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. (Section 6(b)(5))

Sections 2(b)(5) and (6), 20, 21, 22, and 24 of the Act reflect Congress' recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose-response data may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, while final standards are to be based on the best available evidence, the legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d Session, p. 18 (1970). This Congressional judgment is supported by the courts which have reviewed standards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "It remains the duty of the Secretary to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient. "Society of the Plastics Industry, Inc. v. Occupational Safety and Health Administration", 509 F. 2d 1301, 1308 (2nd Cir. 1975), cert. den., sub. nom., "Firestone Plastic Co. v. United States Department of Labor," 95 S. Ct. 1998, 4 L. Ed. 2d. 482 (1975).

A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia in reviewing the standard for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factural determination. Decision-making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.

"Industrial Union Department, AFL-CIO v. Hodgson," 499 F. 2d 467, 474 (D.C. Cir. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare, S. Rep. No. 91-1282, 91st Cong., 2d Sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. "Society of Plastic Industry, Inc. v. Occupational Safety and Health Administration", supra at 1309.

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examinations. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)). The permanent standard for DBCP was developed on the basis of the above legal considerations.

IV. Major Issues

OSHA has concluded from the evidence in the record that DBCP presents a hazard of cancer and sterility to exposed workers. The results of well-designed animal studies indicate DBCP to be a potent carcinogen in two sexes of two mammalian species at two dose levels. Furthermore. DBCP has been found to cause positive results in microbial assays designed to detect chemicals capable of mutagenesis. This evidence, which has not been seriously challenged by any of the participants in the proceeding, leads to the conclusion that DBCP must be regulated as a human carcinogen.

Animal studies have also demonstrated that oral dosages of DBCP induce degeneration of testicular tissue, accompanied by a reduction of sperm count and abnormal sperm cell development.

These testicular effects were confirmed in humans with the recent discovery of sterility and infertility in a large number of male employees exposed to low levels of DBCP in the manufacture and formulation of pesticides. This evidence was also uncontroverted by hearing participants.

Accordingly, OSHA has concluded that the proven carcinogenic and sterilant potential of DBCP warrants limiting exposure to the lowest level feasible. OSHA has therefore established an eight-hour time-weighted average permissible exposure limit of 1 part per billion (ppb). OSHA has concluded, based on evidence presented in the record, that this limit represents the lowest exposure level achievable using present technology.

Additionally, based on evidence that DBCP can penetrate the skin, and that skin exposure is a significant rout of entry, OSHA has prohibited any skin contact with the substance.

The following discussion deals with the major issues involved in the proceeding.

(1) Whether DBCP has been experimentally proven to be a carcinogen

The carcinogenicity of DBCP in both sexes of two mammalian species (rats and mice) at two dose levels has been documented on the record with a study conducted by the National Cancer Institute (NCI) (exhibit 16). For this study, discussed more fully in the preambles to the ETS and the proposal, NCI used 50 animals of each sex of two species at each of two dose levels (400 total experimental animals) in addition to controls. The two dose levels, administered orally, were selected on the basis of a preliminary subchronic toxicity test (exhibit 16, p. 7). The duration of treatments ranged from 47 to 78 weeks (exhibit 16, p.v).

Dr. Elizabeth Weisburger, Chief of the Carcinogen Metabolism and Toxicology Branch of NCI, gave the following testimony at the hearing:

[The] final report indicated that among rats given DBCP, 100 percent in males and 77 percent in females in the high dose had gastric cancer. This is very highly significantly different from the rate in the controls.

At the low dose, 96 percent of the males and 78 percent of the females had stomach tumors. In addition, 62 percent of females on the high dose and 48 percent on the low dose had mammary carcinoma compared to zero among the controls. Also very highly significantly different.

Hemangiosarcomas were also increased in both males and females at the lower dose level. Furthermore, there were many metastases of these gastric tumors which invaded the stomach wall into the peritoneal cavity and throughout the body. (tr 80-81)

Dr. Weisburger went on to state that among mice, 96 percent of the males and 98 percent of the females on the higher dose developed gastric cancer. On the low dose the percentages were 93 and 100 respectively. As in rats, metastases of these tumors were also noted (tr 81). Dr. Weisburger concluded that "the data from this bioassay thus show that DBCP is a carcinogen in two species and both sexes of two species of animals at two dose levels, inducing tumors which were relatively rare in control or untreated animals." (tr 81)

Dow Chemical suggested that the high dose levels used in the NCI study may have influenced the observed incidences of both stomach and mammary tumors (exhibit 5-8). However, interim results of a recent DBCP dietary study conducted by Hazelton Laboratories and sponsored by Dow Chemical demonstrate that carcinogenic effects are apparent even at dose levels "unlikely to have caused irritation sufficient to increase the induction of cancer" (exhibit 5-8, p. 22).

In the Dow experiment, DBCP was administered to the rats in their food in quantities sufficient to provide dose levels of 0, 0.3, 1 and 3 mg/kg/day. The study period lasted for 104 weeks. The preliminary gross autopsy results revealed "tumor-like" lesions in 6 percent (3/54), 31 percent (17/55), and 64 percent (24/37) of the rats at dose levels of 0.3, 1, and 3 mg/kg/day respectively. Three percent (2/63) of the controls developed such lesions (exhibit 5–8, p. 22). These data further confirm the NCI conclusion that DBCP is carcinogenic.

OSHA concludes, therefore, that DBCP has been experimentally proven to be carcinogenic in animals.

(2) WHETHER DBCP HAS BEEN EXPERIMENTALLY DEMONSTRATED TO BE MUTAGENIC

There are indications from in vitro experiments that DBCP may cause mutagenic effects. Rosenkranz (1975) examined the effects of DBCP on two strains of *E. coli* and on two tester strains of *Salmonella typhimurium*, strains of bacteria normally used for mutagenic research. He concluded that DBCP causes positive results in microbial assays designed to detect chemicals capable of mutagenesis (exhibit 4–45, p. 10).

Dr. Arlene Blum, Research Associate in Biochemistry at the University of California, stated at the San Francisco inquiry (exhibit 10, p. 32) and Cincinnati conference (exhibit 9, p. 134) that DBCP also gave positive results using the Ames test, a bacterial screening test designed to detect chemicals capable of mutagenesis. She noted that DBCP produced results similar to those of the substance benzidine, a known human carcinogen (exhibit 9, p. 140).

Furthermore, a high correlation has been found between the results of in vitro mutagenicity tests and long-term animal carcinogenicity studies (exhibit 9, pp. 134, 135). OSHA finds that based on the evidence in the record, which was unchallenged, DBCP has been experimentally demonstrated to be mutagenic.

(3) WHETHER DBCP SHOULD BE REGULATED AS POSING A CARCINOGENIC RISK TO HUMANS

For all practical purposes, the detection of carcinogenic activity of chemicals is based on animal experimentation. Because of the difficulties of epidemiologic studies on humans exposed to potential carcinogens, there are usually no data which provide us definitive evidence as to whether cancer in man is due to a chemical that has been shown to be carcinogenic in animal studies. Moreover, ethical considerations cannot allow human experimentation where cancer is the expected response. However, nearly all chemical substances or mixtures that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals. OSHA maintains, therefore, that a substance which causes cancer in animals must be considered, as a policy matter, as posing a carcinogenic risk to workers. This view has been extensively discussed in other OSHA standards and forms the basis of this agency's and virtually every other agency's regulation of carcinogens. Furthermore, this view was not challenged during the course of the proceeding.

Based on the record, OSHA has concluded that animal experiments have conclusively demonstrated DBCP to be a chemical carcinogen, and therefore to pose a carcinogenic risk to workers. Accordingly in the absence of a demonstrated safe or no-effect level for human exposure to a carcinogen, OSHA believes that it must be assumed as a prudent policy matter, and in light of the scientific evidence available, that no safe level for exposure to DBCP exists (tr. 14–15). After a review of the complete record, OSHA has found no evidence which disputes this reasoning and accordingly concludes that DBCP should be regulated as posing a carcinogenic risk to humans.

(4) WHETHER DBCP HAS BEEN EXPERIMENTALLY SHOWN TO PRODUCE TESTICULAR EFFECTS

In 1961, Torkelson, et al. (exhibit 4–56) conducted experiments in which four animal species (rats, guinea pigs, rabbits and monkeys) were exposed to DBCP by inhalation. The test animals were subjected to 50–66 exposures of 12 ppm DBCP over 70 to 92 days (7 hours per day, 5 days per week). A 40 to 50 percent mortality was observed in the rat study groups which, in most cases, was attributed to lung infections. Examination at autopsy showed damage to the lungs, kidneys, digestive system, and "severe atrophy and degeneration of the testes of all species." In the rats this effect was accompanied by a reduced sperm count, abnormal cell development, and degeneration of the seminiferous tubules. As part of the study 15 male rats were exposed to 5 ppm 50 times in 70 days. At this exposure level the testicular weights of one half the rats were found to be reduced by 50 percent. This result was not statistically significant due to the large internal variation within the group. However, these findings did indicate a need for caution at low exposures to DBCP, and served as the basis for Torkelson's 1 ppm recommendation as a limit for occupational DBCP exposure.

A 1970 study by Faydysh et al. (exhibit 4–22) showed that a 70 mg/kg/day dose of DBCP, administered orally for 45 days, produced a necrotic action on the testicles of white rats.

A report in 1971 by Rakmatullaev (exhibit 4–43) disclosed that chronic (8 month) dietary exposures to DBCP at 5 mg/kg/day produced a distinct decrease in sperm motility (the ability of the sperm to move) for male rats and a decrease in the fertility rate of female rats mated to DBCP-exposed males.

Also, Reznik and Sprinchan reported in 1975 (exhibit 4–78) that acute (single dose, 100 mg/kg) and chronic (10 mg/kg/day for 4–5 months) doses of DBCP severely affected spermatogenesis in male rates.

Based on the above data which was unchallenged on the record, OSHA concludes that DBCP has experimentally produced testicular effects in animals.

(5) WHETHER DBCP HAS CAUSED INFERTILITY IN MALE WORKERS

As mentioned above, fertility studies were initiated in July 1977 as a result of increasing concern among workers of the Agricultural Chemical Division of Occidental Chemical Co. in Lathrop, Calif., that their low birth rate might be related to pesticide poisoning. Preliminary studies performed by Dr. Donald Whorton, a specialist in internal medicine and occupational diseases, indicated a surprising prevalence of abnormal sperm counts (exhibit 4–63) (tr. 223–225). As a result of these findings, NIOSH contracted with Environmental Health Associates to perform a Health Hazard Evaluation (exhibit 26) in August 1977. The results of this evaluation were that of the 107 workers studied, 13.1 percent (14) had azoospermia (no sperm) and an additional 16.8 percent (18) were oligospermic (having an abnormally low number of sperm present in the ejaculate causing infertility) (tr. 233). In a control group of 35 workers, one individual (2.9 percent) was azoospermic and none were oligospermic. Exposure levels at this plant had been found to range from 0.29 to 0.43 ppm as an 8-hour TWA (exhibit 9, p. 150 Tables IV and V). DBCP had been formulated at Occidental Chemical since 1957 (exhibit 10, p. 116).

Also of importance were Dr. Whorton's findings that reduced sperm counts correlated well with the number of months an employee was exposed to DBCP (tr. 232). He found that the longer an employee had been exposed to DBCP, the more likely the worker was to have a reduced sperm count. This evidence indicates a possible dose-response relationship in DBCP's toxic effects. Equally important were Dr. Whorton's findings that the observed sperm counts were the result of massive damage to the cells of the spermatogenic tubule. When viewed microscopically these tubules normally appear full with developing sperm cells (tr. Appendix I, p. 6). In the case of DBCP-affected males, how-

ever, the tubules appear empty (tr. Appendix I, p. 8).

In September 1977, Dow Chemical Co. reported that of 86 employees exposed to DBCP at a production facility in Magnolia, Ark., 24.2 percent (21) were found to be azoospermic, and 30.2 percent (26) were oligospermic (exhibit 9, p. 67-j, 67-k). During DBCP production, 8-hour TWA exposures were measured to range between 0.04 and 0.4 ppm (exhibit 4-77B). No local non-exposed group was studied as a control, but these results do show striking sperm count reduction when compared to those of control groups at other plants. These results, like those of Dr. Whorton, also indicated a correlation between sperm count depression and the degree of DBCP exposure (exhibit 9, p. 57). The duration of DBCP production at Magnolia was from mid-January, 1976 through August 11, 1977 (exhibit 10, p. 188).

In November 1977, Shell Chemical Company announced the final results of fertility tests of employees exposed to DBCP at their Denver and Mobile plants (exhibit 11). At Mobile, of 80 workers tested only 2.5 percent (2) were azoospermic while 13.8 percent (11) were oligospermic. These rates reportedly do not differ from control values. The duration of DBCP production at Mobile, however, was only slightly in excess of one year (April 1976 through July 1977).

At the Shell Denver plant, where DBCP production had begun in 1955 and ended February 1976, the results indicated abnormally low sperm counts. Of the 49 workers tested, 10.2 percent (5) were azoospermic and 14.3 percent (7) were oligospermic (exhibit 11—average of second and third semen analysis). Shell maintained that these data were similar to certain literature values (exhibit 11). However, Dr. Marshall cautioned against such a comparison at the OSHA hearing (tr. 237), indicating that much of the data in the literature may itself reflect a bias toward low sperm counts. For instance, many of the studies did not consider a continence (sexual abstinence) period before semen collection. Dr. Marshall made the point that a standardized continence period for semen collection is necessary in order to make valid comparisons of sperm counts (tr. 239).

A control group of 31 non-exposed Denver employees contained no azoospermics, but a surprising incidence of oligospermia (22.6 percent) (exhibit 11). Attempts to correlate length of exposure with sperm count using these data have not been successful. As a whole, the Denver results seem to indicate a DBCP effect as reflected in the high incidence of azoospermics among exposed employees, but such an analysis cannot be regarded as conclusive.

From the time industrial hygiene measurements were initiated in 1972 through the cessation of DBCP production in 1976, 8-hour TWA exposures at Denver consistently were measured to be in the range of 0.2 to 0.4 ppm (exhibit 9, p. 81).

Dow Chemical also reported, however, that studies on a DBCP-exposed population at their Midland, Mich., plant indicated that the sperm counts of 249 "potentially exposed" workers were comparable to those of 77 controls (exhibit 12). DBCP had been produced at the Midland plant from 1957 to 1976. In 1975, employee 8-hour TWA exposures to DBCP were measured to be between "none detectable" and 0.17 ppm (ehxibit 4-77B) Although these results are encouraging, they do not establish a safe or no effect level. The danger of DBCP exposure at very low levels (see Lathrop and Magnolia) are such as to discourage reliance on a no effect level based on one study.

In December 1977, OSHA was notified by telegram that initial tests had indicated sterility in five workers at Bromine Compounds, Ltd., Beersheva, Israel (exhibit 46-d). No data on levels of exposure has been received. Bromine Compounds, Ltd., had manufactured 300 tons of DBCP annually until production was halted in August, 1977.

A point of controversy on the record was the determination of what sperm count value would constitute oligospermia (an abnormally low number of sperm present in the ejaculate causing infertility). It is, of course, necessary to have some agreed upon standard against which to compare the results of the various studies. Values, indicating an abnormally low sperm count, which were suggested by participants at the Cincinnati conference ranged from ten million to 40 million sperm per milliliter ejaculate (exhibit 9, p.39, 57, 61, 125, 133-c). OSHA has selected for the purposes of this discussion a level of 20 million sperm per milliliter ejaculate below which a man is to be considered oligospermic. This selection was based on the testimony of Dr. Summer Marshall (a urologist in private practice in Berkeley, Calif., and an Associate Clinical Professor of Urology, School of Medicine, University of California at San Francisco) (tr. 236) as well as careful analysis of other expert testimony and literature sources.

Based on the above evidence OSHA concludes that exposure to DBCP has been demonstrated to produce infertility (reduced sperm count) and sterility in male workers at very low levels of exposure.

(6) WHETHER DBCP ALONE WAS THE CAUSAL AGENT OF THE OBSERVED INFERITILITY IN WORKERS

A problem encountered in assessing DBCP-induced infertility was the possibility that the observed effects were due to exposure to other substances present in these workplaces. For example, Dr. Whorton stated at the Cincinnati conference that some 224 chemicals were used in Occidental Chemical's Agricultural Chemical Division (exhibit 9, p. 29). DBCP was, however, immediately suspect at the Occidental plant due to: (1) The large amounts of DBCP handled there, and (2) the Torkelson report which showed substantial effects on rat testicles when atmospheric concentrations of DBCP were as low as 5 ppm. These suspicions were confirmed when the results of semen analyses of employees at the Shell and Dow DBCP plants showed severely depressed sperm counts (exhibit 11) (exhibit 9, p. 67-i, 67k). Although ethylene dibromide (EDB), a chemical which has experimentally been shown to produce reproductive effects in animals, was also being manufactured at Magnolia, this chemical was removed from suspicion by the preliminary results of sperm counts of employees from other EDB-producing plants (exhibit 9, p. 219, 235). These results indicated that the sperm counts of the employees exposed to EDB alone were in the normal range.

Based on the above evidence OSHA concludes that DBCP was the causative agent of the observed sterility and infertility effects in exposed workers.

(7) WHETHER DBCP-INDUCED INFERTILITY IS REVERSIBLE ONCE EXPOSURE HAS CEASED

At the Cincinnati conference Dr. John MacLeod, a nationally recognized fertility expert from Cornell University, discussed infertility studies concerning reversibility that were carried out with bis-dichloro acetyl diamine and X-radiation using prison volunteers. Bis-dichloro acetyl diamine "has similar effects to that of DBCP" in that "you get profound depression in testicular function to the point of azoospermia". This effect was found to be totally reversible, though the time period of recovery was not given (exhibit 9, p. 114-115). Dr. MacLeod also referred to "the extraordinary capacity of the human testes to recover from devastation" following bombardment with high doses of X-radiation (exhibit 9, p. 256). Recovery times were noted as ranging from 18 months to 2 years. However, there is a paucity of data concerning the reversibility of the effects of DBCP. As Dr. Whorton stated at the OSHA hearing:

> We have scant data with which to address the question of reversibility of DBCP-suppressed testicular function. The information that we do have suggests that a reversibility can occur in some cases, but that at some point along the dose-response curve, the damage may be permanent (tr. 234).

The question of the reversibility of DBCP-induced testicular effects therefore remains unanswered at this time.

Even if currently affected workers fully recover at some point in the future, the issue of reversibility is not determinative for regulatory purposes. OSHA can not allow workplace conditions which result in severe physical impairment such as sterility, regardless of possible future reversibility.

(8) DOES SUITABLE TECHNOLOGY EXIST IN ORDER TO COMPLY WITH THE REGULATION?

The technological feasibility of the DBCP standard has been assessed by JRB Associates, Inc. in a report entitled, "Economic Impact Assessment of the Occupational Safety and Health Administration's Standard on Occupational Exposure to 1, 2-Dibromo-3-chloropropane (DBCP)" (exhibit 6).

This study has concluded that compliance with the permissible exposure limit of 1 ppb is technologically feasible (exhibit 6, pp. 4-1). Furthermore, OSHA maintains that it is feasible to achieve ambient levels of 1 ppb solely through the implementation of engineering and work practice controls. These controls consist of totally enclosing the DBCP manufacturing and formulating facilities, maintaining such enclosures under negative air pressure, and removing the DBCP in the exhaust air via charcoal adsorption.

Evidence on the record indicates that DBCP manufacturers now routinely control 8-hour TWA exposures to levels ranging from 40 to 430 ppb in response to an informal exposure limit of 1 ppm (part per million) established prior to a full understanding of the serious nature of the DBCP hazard (exhibit 4-77B; exhibit 9, p. 150 Tables IV and V). Furthermore, the record indicates that these levels were maintained without the use of local exhaust ventilation (exhibit 10, p. 128, 129) or other control techniques. This indicates that there exists a great capacity for exposure reduction.

Moreover, exposure to bischloromethylether, a chemical known to be a human carcinogen, is currently controlled to 1 ppb (exhibit 6, p. 42). Therefore it may be concluded that in certain operations the technology currently exists to control airborne contaminants to ppb levels.

In the finding of feasibility OSHA has considered the relative sophistication of the companies presently manufacturing DBCP. Dow Chemical Co. and Shell Oil Co. are both large organizations with vast experience in the area of exposure control to toxic substances. It is not unreasonable to conclude therefore, that these companies are able to implement state-of-the-art control technologies given sufficient financial incentive to do so. Due to the lack of substitutes for DBCP (exhibit 15, p. 2) and the estimated magnitude of crop losses should DBCP not be available (exhibit 39-2), OSHA finds that such incentives should exist. The economic considerations appear even more favorable in light of the fact that up to the promulgation of the ETS, only two plants were active in the production of DBCP. Control technologies and resources can thus be concentrated in the relatively few workplaces where exposures exist.

OSHA further recognizes that engineering and work practice controls are expensive to implement, and that many formulators may have to cease DBCP operations.

Due to the extremely serious nature of the hazard of exposure to DBCP, the concentration of DBCP formulating operations in those companies capable of providing the necessary protection for their employees is desirable and necessary.

Post-hearing comments received from one DBCP manufacturer suggested that achieving the permissible exposure limit of 1 ppb is not feasible (exhibit 53, p. 6). These comments raised some specific engineering questions regarding the suggested engineering controls including the issues of explosion potential, the amount of charcoal needed, and certain operational requirements for incinerators which may have to be used in the event that the charcoal method is unsatisfactory.

The commenter has asserted that the technological feasibility assessment has failed to consider explosion potential (Exhibit 53, pg. 7). OSHA believes that the potential for achieving concentrations in the explosive range has always existed in chemical production facilities and continues to exist. The addition of an enclosure surrounding the process equipment should not increase the explosion risk during normal production, assuming the process equipment is well maintained and properly operated, and that the engineering controls function properly. Under emergency conditions, such as rupture or leak, any increased explosion risk attributable to the enclosure would be counteracted with controls similar to those that would be needed to guard the process equipment if it were not totally enclosed. These controls would include fixed explosion suppression systems triggered by the detection of potentially explosive mixtures, or similar devices.

In addition, to reduce explosion risk, enclosures should be designed with explosion-proof lighting, exhaust fans, and motors. This type of equipment is routinely used in chemical production facilities and its use is commonly considered good engineering practice. Use of this type of equipment was assumed by JRB in deriving the cost estimates for installing engineering controls. (Exhibit 6, pp. 4-6, 4-7, 4-10, 4-11.)

As to the amount of charcoal required and the lack of available data demonstrating the effectiveness of the charcoal adsorption method (Exhibit 53, p. 7), OSHA does not believe that actual demonstration of the feasibility of charcoal adsorption is necessary. The charcoal adsorption method of air purification is widely used in such applications as air-purifying respirators, laboratory clean rooms, and industrial processes. Furthemore, that charcoal will absorb DBCP is demonstrated by the fact that personal exposure air monitoring methods for DBCP rely on charcoal adsorption. The additional costs for more frequent replacement of the charcoal would be approximately $9,000 per facility per month of operation, a sum which does not alter significantly the conclusions of the JRB report. This figure includes the cost of obtaining additional charcoal, additional labor costs for recharging the adsorber more frequently, and the cost of disposing of the additional used charcoal. The calculations for these additional costs are based on the unit costs presented in the Economic Impact Assessment (exhibit 6, p. 4-8).

The comment that operational requirements and effluent handling requirements for an incinerator to remove DBCP from exhaust air were not assessed in the technological feasibility assessment is not in point. Incineration was identified as an alternate control system in the technology feasibility assessment. Operating requirements for fuel, which is clearly the major operating cost, were estimated at $36,000 per month per incinerator. There is no evidence in the record to support the claim that special equipment would be required to handle effluent from the incinerator.

In light of these arguments, OSHA has determined that the compliance with the standard is technologically feasible by installing engineering controls and implementing work practices. It should be noted that no substantive evidence was put in on the record by affected parties which refutes this conclusion.

OSHA has also found that the sampling and analysis of DBCP airborne concentrations at and below the level of 1 ppb is feasible, and has provided one such method on the record (exhibit 28) and in Appendix B of the final standard. The feasibility of sampling was not controverted on the record, although one commenter indicated that the sampling tubes may have to be refrigerated during shipment to prevent the loss of DBCP from the charcoal adsorbant (exhibit 53, p. 4).

(9) WHAT ARE THE ESTIMATED COSTS OF COMPLIANCE WITH THE DBCP REGULATION?

An economic impact analysis of the DBCP regulation was conducted by JRB Associates, Inc. (exhibit 6). The study has estimated the capital cost of

compliance for each plant manufacturing DBCP to be approximately $1,100,000. Also, additional annual operating costs for each plant manufacturing DBCP have been estimated to be approximately $50,000. There are currently two plants in the United States which manufacture technical grade DBCP.

For formulating plants, the average capital cost of compliance would be on the order of $610,000, and the average increase in annual operating costs would be approximately $12,500.

For employers involved solely in the transportation and distribution of DBCP pesticides, there would be increased compliance costs attributable to labeling, employee training, and emergency planning. These are the only requirements for workplaces dealing only with sealed, intact containers of DBCP. These costs would be on the order of $1,400 per facility in one-time costs for such items as signs, training packages, and an emergency plan.

In addition, these workplaces would incur an additional $600 annually for operating costs including instructor's time, and employees lost time for training, and labels, assuming no more than ten employees per distribution facility needed to be trained (exhibit 6, p. 5-11, 5-17, 5-18). These costs for distribution facilities do not appear in the JRB report, but are calculated based on JRB's estimated costs for labeling, employee training, and emergency planning in manufacturing and formulating facilities. Although the number of workplaces involved in the distribution of DBCP is not known with great certainty, it is believed to be less than 2,000 (exhibit 39-1).

In total, the capital costs of compliance are estimated as $12,300,000 and the estimated annual operating costs are on the order of $1,650,000. When amortizing the capital costs and including the operating costs, the annual cost of compliance is estimated as $3,650,000. The continued production of DBCP, therefore, appears economically feasible in light of the United States Department of Agriculture estimate of $300 million in crop losses should DBCP not be available. Based on all the evidence in the record, OSHA concludes that compliance with the standard is economically feasible. Post-hearing comments have been received from one manufacturer of DBCP asserting that the cost of complying would exceed the threshold value used by the Department of Labor for defining a "major" economic impact and therefore, additional economic analysis should be performed (exhibit 53, pp. 6-8). This assertion is based on additional costs of compliance projected for employers involved in the transportation, distribution, and application of DBCP pesticides. In addition, these comments have asserted that the installation of required engineering controls would result in a delay of 2-3 years before DBCP could be made available to the American farmer, and the crop loss attributed to such delay would be on the order of $300 million per year (exhibit 39-2).

OSHA finds that these assertions are not valid. With respect to the transportation and distribution of DBCP, those establishments dealing only with sealed containers of DBCP are required to comply with only the emergency, labeling, and employee training provisions. This constitutes a modification from the proposed standard on which the above mentioned comments were based. Therefore, although there will be some additional cost of compliance with the final standard for distribution facilities, these costs would not likely include the construction of separate facilities or the installation of shower and change room facilities, as the commenter has asserted, except where DBCP exposures can be reasonably anticipated. OSHA estimates the capital cost of compliance for DBCP distribution facilities to be approximately $1,400 per facility. In addition, OSHA estimates annual operating costs to be approximately $600 per facility. If these costs were added to the estimates provided by JRB to estimate the total cost to industry of compliance with the standard, the resultant total cost estimates still do not approach the threshold value used by the Department of Labor for defining "major" economic impacts.

The commenter's assertion that there will be increased compliance costs for DBCP applicators is incorrect. Applicators are exempt from coverage by the DBCP standard.

One commenter has asserted that there will be crop losses caused by delay in instituting engineering and work practice controls (exhibit 53). This assertion is believed by the provisions of the standard, which permits employers to provide respirators where engineering and work practice controls are not yet sufficient to reduce employee exposure within the permissible exposure limit. OSHA recognizes that there will necessarily be some lost time in DBCP producing and formulating facilities while engineering controls are being installed. However, since DBCP production and formulation is generally performed on a seasonal basis, rather than continually, it seems reasonable to conclude that the necessary engineering modifications could be made while DBCP would not otherwise be formulated, and that DBCP pesticides could be made available for distribution during the period when controls were being installed. Also, the standard does not prohibit the use of DBCP presently stockpiled by manufacturers. Therefore, there is no reason to believe DBCP will be unavailable because of the OSHA standard.

(10) PERMISSIBLE EXPOSURE LIMIT

On the basis of the observed carcinogenic and sterility effects of DBCP, OSHA has selected an 8-hour time-weighted average (TWA) permissible exposure level (PEL) of 1 part DBCP per billion parts air (ppb). Also, based on uncontroverted evidence that DBCP may be absorbed through the skin (exhibit 4-66), (exhibit 2-3, p. 5), OSHA has concluded that all skin contact with DBCP be prohibited.

There is no dispute that DBCP has been shown to be a highly potent carcinogen in animal experiments. However, any dose-response extrapolations of these results to human exposures are not possible using current scientific precepts, and the question of whether a "no effect" level exists with respect to carcinogenicity has not been answered on the record. No data is presently available to indicate that any given level of exposure to DBCP would, in fact, be free of carcinogenic risk to exposed individuals. However, even if specific levels of exposure could be demonstrated to be associated with the incidence of cancer, this could not, in and of itself, establish a safe level for exposure to DBCP. While specific thresholds to various carcinogens may theoretically exist for some individuals, such thresholds may vary substantially within any given population at risk as well as with time. Furthermore, the long latency periods involved in carcinogenesis make it difficult to demonstrate that an exposure level which appears not to induce cancer in the short run is in fact safe; 5-40 years may be required before exposure to a carcinogen might produce detectable cancers. However, since nearly all chemicals that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals, OSHA maintains that a substance which causes cancer in animals must be considered as posing a carcinogenic risk to workers.

The record also contains definitive evidence that DBCP has induced sterility and infertility in exposed workers. These effects were found to occur even at very low exposures ranging from 40 to 430 ppb DBCP. OSHA has found, however, that adequate epidemiologic data does not exist which provides sufficient information to accurately predict a "safe" or "no effect" level, assuming one exists, with respect to the sterilant effects of DBCP.

Therefore, considering (1) the very low levels at which DBCP induced sterility has been found to occur; (2) the remarkable carcinogenic potency of DBCP as demonstrated in animal experiments; (3) the nature of the haz-

ards of DBCP exposure, namely sterility and cancer; and (4) the inability to determine an exposure level that will eliminate the risk of cancer and sterility, OSHA deems it necessary to set the permissible exposure limit for DBCP at the lowest level technologically feasible.

Within the confines of feasibility OSHA has determined that a permissible exposure limit of 1 ppb as an 8-hour TWA best minimizes the cancer and sterility hazards of DBCP.

The record indicates that DBCP exposures are now controlled in manufacturing and formulating operations to levels ranging from 40 to 600 ppb. Furthermore, these levels have been achieved without prior knowledge of the severe hazards of DBCP exposure and, therefore, without the full utilization of highly sophisticated engineering controls.

Evidence on the record also indicates that an economic incentive exists for the continued production of DBCP. Compliance costs have been estimated to be on the order of $1,100,000 capital and $50,000 annual costs for manufacturing facilities, and $610,000 capital and $12,500 annual costs for formulating facilities. These costs are well below the estimate of $300,000,000 annual crop loss should DBCP not be available. Furthermore, for the post-plant control of nematodes, no suitable substitutes for DBCP have been found to exist. The unavailability of substitutes indicates that compliance costs for manufacturers and the formulators should be recoverable through increases in the price of DBCP to the consumer.

DBCP is also manufactured on a relatively limited production scale. Only two plants were engaged in DBCP production up to the time of the promulgation of the ETS. It has also been estimated that with a 1 ppb permissible exposure limit, only six formulators will continue to formulate DBCP. The concentration of DBCP production and formulation facilities further enhances the economic feasibility of compliance since such a market structure would better allow the pass through of compliance costs to consumers benefiting from DBCP use.

Shell Oil Co. and Dow Chemical Co., the two companies operating DBCP production facilities up until the promulgation of the ETS, are large organizations with considerable expertise in the control of exposures to toxic chemicals. OSHA concludes that these companies are in a position to provide the control equipment necessary to reduce DBCP exposure to permissible levels.

In the analysis of feasibility OSHA has considered (1) the levels of DBCP exposure attainable using existing controls; (2) the sophistication of existing control methodologies; (3) the economic incentives for continued DBCP production, including the costs of compliance, the inelasticity of demand, the limited scale of production, and the possible changes in market structure with respect to DBCP; and (4) the relative sophistication of the companies producing DBCP with respect to control technology. In light of these considerations OSHA finds that, for employee exposures to DBCP, a permissible exposure limit of 1 ppb is both technologically and economically feasible.

V. Summary and Explanation of the Standard

The final standard for occupational exposure to DBCP substantially reflects the provisions of the proposal (42 FR 57266) with two major exceptions.

The final standard, unlike the proposal, contains a limited exemption for workplaces where DBCP is present only in sealed, intact, containers. OSHA has determined that the likelihood of exposure and potential health risks to employees handling DBCP in sealed, intact containers does not justify the implementation of the more stringent provisions of the standard such as routine monitoring and medical surveillance. Moreover, such requirements are not necessary for the protection of employees handling sealed, intact, containers of DBCP. Accordingly, only the labeling, training and emergency provisions of the final standard apply to the storage, transportation, distribution and sale of sealed, intact containers of DBCP.

Also, OSHA has decided to delete the ceiling exposure requirement from the final standard. OSHA believes that compliance with the exposure limit of 1 ppb over an 8-hour day effectively limits the magnitude of short term exposures. For instance, a 30-minute exposure to 16 ppb DBCP, with no further DBCP exposure that day, represents a daily dose equal to an 8-hour exposure to 1 ppb.

All other language changes in the final as compared to the proposed standard are essentially non-substantive and are intended only to enhance the clarity of the particular requirement with respect to employer and employee understanding as well as enforceability of the provision.

Few comments or objections to the specific provisions of the standard were received. Where issues were raised in the course of the proceeding, they are discussed in the explanation of the major provisions of the standard which follows.

1. Paragraph (a)—*Scope and application.* The standard applies to all employments where DBCP is present with the two exceptions discussed below. The principal activities covered include the manufacture of DBCP, the formulation of pesticides containing DBCP, and related activities of packaging, repackaging, storage, transportation, and disposal of DBCP.

OSHA has determined that the storage, transportation, distribution and sale of sealed, intact containers of DBCP should be subject only to the labeling, training, and emergency provisions of the final standard. This is a change from the proposed standard and the ETS which did not contain the limitation. Participants in the rulemaking pointed out that the proposal would require employers to monitor exposure and require medical surveillance of employees who have only casual or limited contact and no discernible exposure to DBCP. Examples of such employees are maritime employees occasionally handling sealed drums of DBCP (exhibit 5-5) or distributors, jobbers and employees of retail outlets (exhibit 5-7). This limited exemption serves to maximize employee protection while minimizing unnecessary burdens.

The final rule distinguishes between "closed," and "sealed," containers. OSHA is concerned that containers, after being opened, may be closed in such a fashion as to expose employees to DBCP. For this reason, the exemption applies only to "sealed" containers, intending by the use of that term to exempt only containers of DBCP which are closed in such a manner as to contain the DBCP vapors. Additionally, since sealed containers may, during handling, develop leaks, the exemption is further limited to intact containers.

Therefore, where breakage of the container occurs, employers will be required to monitor, provide protective equipment and medical surveillance, and to comply with any other applicable provisions of the standard. To assure that all employees are aware of the hazardous nature of the contents of the containers, and are familiar with appropriate procedures for handling in case of emergency exposure, and because at some point in downstream occupational activities the containers will be opened, the training, labeling and emergency provisions apply to the handling of sealed, intact containers.

Finally, it should be noted that the regulation of sealed containers in this standard is consistent with that in other carcinogen standards (§§ 1910.1003-1910.1016) and the recently promulgated benzene standard (43 FR 5918).

The standard does not apply to exposures which result solely from the application and use of DBCP as a pesticide. On September 8, 1977, concurrent with OSHA's issuance of the ETS, the Administrator of the Environmental Protection Agency announced his intention to take two sus-

pension actions with respect to pesticide products containing DBCP (42 FR 48915), pursuant to his authority under section 6(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (FIFRA). This Act allows the Administrator to suspend the registrations of a pesticide product whenever he determines that such action is necessary to prevent an "imminent hazard" during the time required for cancellation or change in classification proceedings.

On October 27, 1977, EPA issued a suspension order (42 FR 57543) which effected two suspension actions: A suspension of all pesticide products registered for food crop uses with respect to which residues of DBCP have been found or are anticipated on the edible portions of the food crops; and a conditional suspension with respect to all uses, based upon the Administrator's finding that an imminent hazard exists for pesticide applicators if DBCP products are used in accordance with current label restrictions.

The regulatory actions announced by EPA will have two important effects leading to increased protection of workers engaged in the application and use of DBCP as a pesticide. First, the suspension of use of DBCP pesticides for certain food crops will substantially reduce the number of applicator personnel and field workers who would otherwise have been exposed to DBCP.

Second, under the conditional suspension announced for all other uses, persons using DBCP for other uses will have to be certified applicators (and in some instances certified commercial applicators), or be working under the direct supervision of a certified applicator. Additionally, persons using DBCP for conditionally suspended uses will be required to wear protective clothing and respirators.

OSHA believes that this strategy of combined and cooperative regulatory actions by both EPA and OSHA is an effective approach to protecting all workers against the hazards of exposure to DBCP. Accordingly, this standard does not apply to exposures to DBCP which result solely from its application and use as a pesticide.

2. Paragraph (c)—*Permissible exposure limit.* The standard establishes a permissible exposure limit of 1 part DBCP per billion parts of air (1 ppb) as an 8-hour time-weighted average.

As discussed more fully above, the reported exposure of employees at concentrations significantly less than one part per million at several manufacturing and formulating plants and the resulting sterility in a substantial proportion of the exposed employees even at that level clearly indicates that a substantial reduction in exposure must be accomplished to mitigate the risk. There is, unfortunately, not complete information on the exact level necessary to eliminate the risk. Here, we cannot determine whether there is a safe level or threshold level below which reproductive effects would not occur.

Evidence from several animal tests in mammalian species conclusively demonstrates the carcinogenicity of DBCP.

OSHA policy, which is based on the best available scientific evidence, and which is consistent with the policies and recommendations of nearly all public bodies which have addressed the problem of exposure to cancer-causing substances, has been and is that a substance which causes cancer in animals must be regulated as posing a carcinogenic risk to workers. In the absence of a demonstrated "safe" or "no effect" level for human exposure to a carcinogen, it must be assumed, as a prudent policy matter, that no safe level exists.

Accordingly, the setting of an exposure level for DBCP cannot be based on a determination of a "safe" level which will eliminate the cancer and sterility hazard, but rather on a determination of a level which will minimize these hazards to the greatest extent possible, within the confines of feasibility.

Based on evidence that DBCP is absorbed through the skin, OSHA prohibits all skin contact with DBCP.

For the final standard, OSHA has not included the provision for a 15 minute ceiling exposure limit of 10 ppb which appeared in the proposal. OSHA believes that compliance with the exposure limit of 1 ppb over an eight-hour day effectively limits the magnitude of short term exposures.

Our assessment of technological feasibility, discussed above, indicates that an exposure limit of 1 ppb is technically feasible for both DBCP manufacturing and formulation operations (see exhibit 6, p. 4-1).

OSHA believes that isolation of workers from the process equipment may be necessary to minimize exposure to DBCP, and that this can be accomplished by totally enclosing the equipment in a building or in a separate room within a building. Automatic or remote control of the different loading, process, and packaging operations would be necessary, to eliminate any requirement for workers to enter the enclosure during the operation (exhibit 6, p. 4-4).

3. Paragraph (d)—*Notification of use.* The ETS required employers to notify the OSHA Area Director of the location of workplaces where DBCP is present, and to describe the conditions of use and exposure and the protective measures in effect. The standard does not require employers to report the same information again. Rather, any employer who has not yet notified the OSHA Area Office or who subsequently introduces DBCP into a workplace is required to report to the Area Director in the same manner as required by the ETS.

4. Paragraph (e)—*Regulated areas.* The standard requires the establishment of regulated areas where airborne concentrations of DBCP are in excess of 1 ppb. The purpose of establishing regulated areas is to limit DBCP exposures to as few employees as possible by barring access to these areas to all but those specifically authorized to be in the area. OSHA believes that control of employee exposures, appropriate exposure monitoring, medical surveillance, and limitation of potential exposure to the smallest number of workers all require regulated areas. The employer must designate as "authorized" any person whose duties require his or her presence in the area.

5. Paragraph (f)—*Exposure monitoring.* Section 6(b)(7) of the Act (29 U.S.C. s655) mandates that any standard promulgated under 6(b) of the Act shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of monitoring are to determine the extent of exposure, to identify the source of exposure, to enable the employer to select proper control methods and to evaluate the effectiveness of the selected methods. Thus, monitoring enables employers to meet the legal obligations of the standard to assure that their employees are not exposed to DBCP in excess of the prescribed levels. Additionally, monitoring enables employers to notify employees of their exposure level, as required by section 8(c)(3) of the Act, and to provide information necessary to the examining physician.

The exposure monitoring provisions intend that the employer determine the exposure for each employee exposed to DBCP. This does not require separate measurements for each employee. If a number of employees perform essentially the same job under the same conditions, it may be sufficient to monitor a significant fraction of such employees and obtain results that are representative of the exposures of the remaining employees.

Where exposures are determined to be above the permissible exposure limit, the employer is required to monitor monthly. Otherwise the employer must monitor quarterly. "Exposure" in this connection means the airborne concentrations in the workers' breathing zone, without regard to the use of respirators.

The employer is also required to redetermine the exposure of affected employees by monitoring if any

changes in production, processes, control measures or personnel occur which might cause new or additional exposures to DBCP.

One commenter stated that the required frequency of monitoring does not take into account the stability of airborne concentrations, and that in closed-system operations such frequent and repeated personal monitoring may be unnecessary (exhibit 4–8, p. 9). OSHA finds, however, that frequent monitoring is crucial considering the very low magnitude of the permissible exposure limit. Small leaks in control equipment, which may not be detectable during routine visual inspection, could lead to exposures well in excess of 1 ppb. The fact that DBCP has no detectable odor until 180 ppb, 180 times the permissible exposure limit, further supports the need for frequent monitoring.

An assessment of available methodology for sampling and analysis of airborne concentrations of DBCP indicates that it is possible to monitor employee exposures of 1 part per billion and below (tr. 317). Furthermore, at these concentrations sampling and analytical methodologies are available which have an accuracy, to a confidence level of 95 percent, of not less than plus or minus 25 percent. Using one method, for example, the samples may be collected by adsorption of DBCP on charcoal contained in a suitable holder such as glass tubing through which a volume of air is drawn. Analysis is then performed by gas chromatography, using electron-capture detection. These techniques, although they require care, are readily available and should pose no special difficulties for employers covered by this standard (tr. 319).

6. Paragraph (g)—*Methods of Compliance.* The standard requires the employer to institute engineering and work practice controls to reduce employee exposures to or below the permissible limit. This requirement is in accord with OSHA's policy that feasible engineering and work practice controls must be used as the primary methods of reducing employee exposures to toxic substances. This policy is based on the view that the most effective means of controlling employee exposures is to contain emissions at their source through use of mechanical means, combined with work practices, rather than reliance on the variability of human behavior so critical to the successful use of respirators.

In situations where engineering and work practice controls do not reduce exposures to the permissible exposure limit, these controls must nonetheless be used to reduce exposures to the lowest feasible level and be supplemented by the use of respirators. OSHA realizes that, under some particular circumstances, engineering and work practice controls may not be technologically feasible in a particular work operation. Therefore, the standard explicitly recognizes that an employer may demonstrate the infeasibility of engineering and work practice controls as to one or more operations in a particular process, and in these circumstances use respirators to provide the required protection. The question of whether an employer has met his burden of establishing that engineering and work practice controls are infeasible in a particular work operation involves the consideration of many complex factors and a rational balancing process. Factors such as levels of exposure, useful remaining life of the equipment and the effort made by the employer to implement such controls are relevant.

Respirators are the least satisfactory means of control because of certain difficulties inherent in their use. Respirators are capable of providing good protection only if they are properly selected for the concentrations of airborne contaminants present, properly fitted to the employee, worn by the employee and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. As a consequence, the protection of employees by respirators is not always effective.

In addition, a compliance program to reduce exposures to within the permissible exposure limits solely by means of engineering and work practice controls must be developed and implemented when the engineering and work practice controls presently being used do not reduce employee exposures to within the permissible exposure limit. Written plans for this program must be developed and furnished upon request to representatives of the Secretary, representatives of the Director, and affected employees. These plans must be reviewed and updated periodically to reflect the current status of the program.

7. Paragraph (h)—*Respirators.* The final standard provides that, whenever the permissible exposure limit is exceeded, in spite of implementation of all feasible engineering and work practice controls, the employer must provide and assure that employees use respirators. The standard contains a respirator selection table (Table 1) so the employer will provide the type of respirator which affords the proper degree of protection based on airborne concentrations of DBCP to which the employee may be exposed. The respirator selections in the final standard are identical to those in the proposal.

The standard restricts the selection of respirators to atmosphere-supplying respirators. One participant commented that atmosphere-supplying respirators are cumbersome, restrict movement, and, in the case of self-contained breathing apparatus, require frequent changing of air cylinders (Exhibit 4–8, p. 10). OSHA does not deny the difficulties of use of atmosphere-supplying respirators. However, DBCP does not have any useful warning properties at concentrations where air-purifying respirators may be safely used, and consequently, there is no warning of respirator leakage or breakthrough. The odor threshold of DBCP is estimated to be 180 ppb (exhibit 4–8, p. 10), 180 times the permissible exposure limit. Because of the extremely serious consequences to employee health which have been found in human exposures at 40 to 430 ppb (exhibit 9, p. 150 Tables IV and V) (exhibit 4–77B), we believe it imperative to minimize the risk of undetected exposure, and accordingly permit only atmosphere-supplying respirators.

The standard requires that the employee be properly trained to wear the respirator, to know why the respirator is needed and to understand the limitations of the respirator. An understanding of the hazards involved is necessary to enable the employee to take steps for his or her own protection. The respiratory protection program implemented by the employer must conform with 29 CFR 1910.134 (b), (d), (e), and (f). This section contains the basic requirements for use, cleaning, and maintenance of respirators.

To prevent skin irritation and to minimize the discomfort of respirator use, the standard requires that employees must be allowed to periodically wash their faces and respirator facepieces in order to remove any accumulation of DBCP or to reduce the chance of irritation from the wearing of the facepiece itself, such as a heat rash.

The standard requires that respirators and other clothing and equipment required for protection from exposure to DBCP shall be provided at no cost to the employee. OSHA has allocated the costs of respirators and clothing and equipment required for protection from DBCP exposure to the employer in order to effectuate the purposes of the Act. This language clarifies OSHA's position which has long been implicit in health standards proceedings under section 6(b) of the Act.

8. Paragraph (i)—*Emergencies.* This provision requires employee evacuation and cleanup where spills or leaks occur. Only employees with appropriate respirators and impermeable protective clothing are allowed in the area until the situation is restored to normal. It is important to note that all employees covered by the standard, including those who handle only sealed, intact containers of DBCP, are covered by the emergency provisions.

The employer must also provide the medical surveillance testing as specified by paragraph (m) (6) to any employee exposed to an emergency release of DBCP.

9. Paragraph (j)—*Protective clothing and equipment.* The standard requires that the employer provide and assure that employees who are subject to any possibility of skin or eye contact use impermeable protective clothing or equipment in order to minimize these hazards. OSHA is aware that since many formulating and producing facilities are located in warm climates, as a practical matter the impermeable protective clothing requirement may necessitate use of full body air-conditioned suits.

Evidence onthe record indicates that DBCP may be absorbed through the skin (exhibit 4–56), and that even very small amounts of DBCP on the skin are potentially hazardous (exhibit 4–8, p. 5). Therefore the standard requires the prompt removal of protective clothing and equipment which becomes contaminated with DBCP-containing liquids or solids. The standard also provides that this clothing and equipment must not be reworn until the DBCP has been removed from the clothing and equipment. Under no circumstances may clothing and equipment contaminated with DBCP-containing liquids and solids be worn into lunchrooms or lavatories.

The standard also requires that the employer clean, launder, or dispose of the required protective clothing to eliminate any potential exposure that might result were the clothing to be laundered by the employee at home.

The standard requires that protective clothing be provided in a clean and dry condition daily. Since skin contact with DBCP creates a potential for skin absorption, OSHA believes that the regular cleaning of contaminated work clothing plays an important role in the protection against the hazard. The standard also requires that protective clothing and equipment be maintained and replaced as needed in order to ensure effectiveness.

The standard provides that the employer assure that all protective clothing is removed at the end of each work shift, and that the clothing that is to be laundered, cleaned, or disposed of be placed in a closable container. The container must be constructed so as to prevent the release of DBCP vapors into the atmosphere. The purpose of this requirement is to prevent the contaminants on the clothing from being released into the ambient air or from being contacted by an individual handling the container.

Finally, the standard requires employers to inform those who handle the contaminated protective clothing of the potentially harmful effects of exposure to DBCP. This provision is designed to make clear the need to use proper care in handling of the contaminated protective clothing.

10. Paragraph (k)—*Housekeeping.* Removal and prevention of visible accumulations of liquid deposits of DBCP, or dusts containing DBCP, on all surfaces are important aspects in minimizing employee exposure. To assure that DBCP is not reintroduced into the workplace air, the standard prohibits dry sweeping or the use of compressed air for cleaning floors and other surfaces where DBCP is found. The standard also requires that when DBCP is present in liquid form, or as a resultant vapor, that all containers or vessels be enclosed to the maximum extent feasible and tightly covered when not in use to prevent the release of DBCP vapor into the work atmosphere.

For disposal of waste scrap, equipment or debris containing DBCP, the standard requires that this material be collected and disposed of in sealed or closed containers which prevent the dispersion of DBCP outside the containers. State environmental protection agencies designate appropriate landfills for the disposal of such waste.

11. Paragraph (l)—*Hygiene facilities and practices.* The standard specifies hygiene facilities and practices required for employee protection.

Change rooms are required, with separate storage for street and work clothing. OSHA believes that these facilities are necessary to minimize possible contacts with contaminated clothing, since DBCP is skin absorbable, and an irritant as well.

The standard requires the employer to provide shower facilities for employees, and that employees be required to take showers at the end of the workshift to remove any DBCP from their bodies. Section 1910.141(d) (3), which would be triggered by the standard, lists requirements for adequate showers.

The standard also requires that lavatory facilities which comply with § 1910.141(d) (1) and (2) be provided in sufficient number to assure that sufficient facilities are available for employees to wash when leaving the regulated area to eat or use toilet facilities.

The standard prohibits eating, smoking, drinking, or the keeping of food or smoking materials in regulated areas. Additionally, the standard prohibits the keeping of cosmetics in regulated areas to avoid the possibility that DBCP contaminated cosmetics would be inadvertently applied to the body.

The standard requires employers to provide lunchrooms free of DBCP contamination which are readily accessible to employees working in a regulated area. The purpose of this requirement is to minimize the risk of employee exposure to DBCP by ingestion or inhalation during eating.

13. Paragraph (m)—*Medical Surveillance.* Pursuant to section 6(b)(7) of the Act, the standard requires that each employer institute a medical surveillance program for all employees who work in regulated areas. OSHA believes that a medical surveillance program is necessary in dealing with the problem of employee exposure to DBCP.

The standard requires an opportunity for a medical examination for each employee before the first assignment to work with DBCP and annually thereafter. Where employees have received medical examination under the provisions of the ETS, the examination need not be repeated until one year from the date of that examination.

All examinations and procedures are required to be performed by or under the supervision of a licensed physician and provided without cost to the employee. While the physician will usually be selected by the employer, the standard does not so mandate, leaving the employer free to institute alternative procedures such as joint selection with the employee or selection by the employee. Clearly, a licensed physician is the appropriate person to be conducting a medical examination, and such a requirement is contained in the standard. However, certain parts of the required examination (e.g. taking of a history) do not necessarily require a physician's expertise and may be conducted by another person under the supervision of the physician.

The standard provides that a work history, medical history and medical examination be performed. The content of the examination is consistent with identification of the adverse health effects that have been associated with exposure to DBCP.

A commenter suggested that a standardized procedure be mandated for the collection of sperm and subsequent sperm count procedures (exhibit 53, p. 1). Recognizing that differing procedures may produce equally valid results, OSHA chose not to require specific sperm count procedures in the standard. Rather, a suggested protocol has been included in Appendix C.

Both the ETS and the proposal required measurement of serum testosterone levels. This requirement has been eliminated in the final on the basis of evidence that serum testosterone levels do not correlate with DBCP-induced toxicity (tr. 232–233).

Though evidence indicates that sperm counts are the best indicators of DBCP toxicity, the record indicates that the determinations of serum levels of follicle stimulating hormone (FSH), luteinizing hormone (LH), and,

in the case of females, estrogen, are also important in fertility assessment (tr. 232, 233) (exhibit 9, p. 41-45). These tests are especially important for females, vasectomized males, and other males unable to produce a semen specimen.

The emergency medical surveillance provisions reflect OSHA's concern for those employees who, because of equipment breakdown, container rupture or other causes, may be exposed to massive doses of DBCP. These workers may be at a relatively high risk for developing adverse fertility effects.

If a worker is exposed to an unexpected release of DBCP, the employer must, as soon as practicable, provide the employee an opportunity for a sperm count, or, in instances where an employee is unable to produce a semen specimen, a determination of serum levels of FSH, LH and estrogen (females). The employer is also required to provide these procedures three months later. The purpose of the three month repeat is that evidence on the record indicates that, since sperm take three months to mature, testicular damage would not be reflected in sperm count results until that time. The initial results would then serve as a baseline against which the repeat result could be compared.

The standard requires that the employer provide the physician with certain information. This includes: (1) A copy of the regulation; (2) a description of the affected employee's duties as they relate to the employee's exposure; (3) the results of the employee's exposure monitoring; (4) if any personal protective equipment is used or is to be used; and (5) information from previous medical examinations of the affected employee to the extent that they are not readily available to the physician. The purpose of making this information available to the physician is to aid in evaluation of the employee's health in relation to his assigned duties, and fitness to wear personal protective equipment when required.

The employer would be required to obtain and provide the employee with a written opinion from the examining physician containing: (1) The results of the medical tests; (2) the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to DBCP; and (3) any recommended limitations upon the employee's exposure to DBCP and upon the use of protective clothing and equipment such as respirators. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to DBCP. A copy of the opinion must be provided to the affected employee by the employer.

The requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the results of the medical examination and may take any appropriate action. The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure be excluded from the written opinion is to encourage employees to submit to medical examinations by removing the fear that employers may find out adverse or embarrassing information about their physical condition that has no relation to occupational exposures.

Among the issues in the DBCP rulemaking were whether OSHA should include a mandatory removal requirement—that is, a provision prohibiting the exposure of an employee to DBCP if the employee would be placed at increased risk of material impairment to health because of such exposure, and whether OSHA should include a rate retention provision—that is, a provision requiring the transfer of such employee to another job or providing that removal for medical reasons should not result in loss of earnings or seniority status to the affected employee. These issues, as OSHA has previously stated (41 FR 46780), are related and must be addressed together. Both employee and industry participants expressed their views as to several aspects of these issues in prehearing comments, in testimony during the hearing and in post hearing arguments. However, OSHA has conducted an informal public hearing on mandatory removal and rate retention for workers exposed to lead as part of the rulemaking proceeding on lead. Consideration of the critical issue of medical removal protection is being undertaken for several pending standards together. Once this consideration is completed, OSHA will determine the extent to which the conclusions on medical removal protection are appropriate for DBCP and whether to include those or similar provisions in the DBCP standard. The final standard published today, therefore, does not address the issues of mandatory removal and medical removal protection.

13. Paragraph (n)—*Employee information and training.* The standard requires the employer to provide a training program for employees potentially exposed to DBCP. OSHA believes that an information and training program is essential for the protection of employees, because an employee can do much to protect himself if informed of the nature of the hazards in the workplace. To be effective, an employee education system must, at the minimum, apprise the employee of the specific hazards associated with his work environment. For this reason, the employer would be required to inform each employee potentially exposed to DBCP of the nature of the related health problems, the necessity for exposure control, emergency procedures, and the medical and industrial hygiene monitoring programs.

The content of the training program is intended to apprise the employees of: (1) The hazards to which they are exposed; (2) the necessary steps to protect themselves, including avoiding exposures, using respiratory protection and availing themselves of the opportunity for medical examinations; (3) their role in reducing exposures; and (4) the contents of the standard. Section 6(b)(7) of the Act makes it clear that these are appropriate goals of an employee training program, and the standard, therefore, includes them.

The employer is also required to provide to the Secretary and the Director, upon request, all materials relating to the training program. This is intended to provide an objective check of compliance with the requirements of the standard.

14. Paragraph (o)—*Signs and labels.* OSHA believes that it is important, and section 6(b)(7) of the Act mandates, that appropriate forms of warning, including labels, be used to assure that employees are apprised of the hazards to which they are exposed in the course of their employment. OSHA believes, as a matter of policy, that employees should be given the opportunity to make informed decisions as to whether to work at a job under a particular set of working conditions. Furthermore, OSHA believes since control of safety and health problems involves the cooperation of employees, success of a safety and health program is highly dependent upon the employee's understanding of the hazards involved in the job.

In light of the serious nature of the hazard of exposure to DBCP, OSHA does not believe that periodic training alone will adequately apprise employees of the health hazards of DBCP. However, OSHA believes that the requirement to post warning signs and labels when coupled with the training requirements discussed above will adequately do so.

The standard requires that nothing which contradicts or detracts from the effect of any sign required by this paragraph shall appear on or near any such required sign.

Due to the hazardous nature of exposure to DBCP, OSHA believes that emphasis should be placed on warning employees and other persons about the danger of exposure. For this reason, the standard includes a requirement that warning labels be affixed to all containers containing DBCP or products containing DBCP. The labeling provisions of the standard also require the employer to assure that warning labels are affixed

to any product containing DBCP when such product leaves the employer's workplace. This requirement is designed to protect any other employees who will be handling, transporting, or using this product. When an employer manufactures, formulates or sells a product containing a toxic substance, that employer is exposing not only his own employees but also the employees of other employers involved in handling, transporting or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulator or seller will in many cases be the only employer capable, through his unique knowledge of the substance, of providing the information needed for protection of other employees. (See the discussion in the recently promulgated benzene standard, 43 FR 5918, 5960.) However, where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph for products leaving the workplace need not be affixed. OSHA feels that the EPA labels adequately alert downstream employers and employees to the hazards of DBCP.

15. Paragraph (p)—*Recordkeeping.* Section 8(c)(3) of the Act provides for the promulgation of regulations requiring employers to maintain accurate records of employee exposure to potentially toxic or harmful physical agents which are required to be monitored or measured. Accordingly, the final standard requires that employers keep records of both monitoring and medical surveillance.

The standard provides that records must be kept to identify the employee and to accurately reflect the employee's exposure. Specifically, it must include: (a) The names, social security numbers and job classifications of the employees monitored, (b) the dates, number, duration and results of each of the samples taken, including a description of the representative sampling procedure used to determine employee exposure where applicable, (c) the type of respiratory protective devices worn by the employee, if any, and (d) a description of the sampling and analytical methods used, and evidence of their accuracy.

The required retention time for medical surveillance records and exposure monitoring records would be extended to 40 years or the duration of exposure plus 20 years, whichever is longer. Carcinogenic induction, if it occurs in an exposed human population, has usually been found by medical surveillance 20 to 40 years after initial exposure. While present medical knowledge does not permit the establishment of exposure limits for carcinogens based on scientific information of the mechanism of carcinogenic induction, it is quite possible that such fundamental scientific knowledge will be developed within the next decade or two. At that point, knowledge of exposure levels of employees will be significant for both developing scientifically valid exposure limits, and for more precisely determining whether exposures may be safely continued for such employees, or perhaps safely raised.

The standard also requires that the employer keep an accurate medical record for each employee who is subject to medical surveillance. Section 8(c)(1) of the Act authorizes the promulgation of regulations requiring an employer to keep such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational illnesses. OSHA believes that medical records (like exposure monitoring records) are both necessary and appropriate to both the enforcement of the standards and the development of information regarding the causes and prevention of illness.

As explained above, it is necessary to relate employees' medical conditions to their exposure in order to develop information regarding cause and prevention. Medical records are necessary and appropriate for this purpose. Medical records are also necessary for the proper evaluation of an individual employee's health as well as providing a baseline against which the results of subsequent examinations may be compared. For all of these reasons, medical records are required.

The standard requires that employees or their designated representatives be provided access to examine and copy records of required monitoring. The purpose of this provision is to assure current employees that their exposure is being properly monitored and recorded, and that they are working in a safe and healthful environment. This is consistent with section 8(c)(3) of the Act which directs the Secretary to promulgate regulations providing "employees or their representatives with an opportunity to observe monitoring or measuring and to have access to the records thereof".

Exposure monitoring records indicating their own exposure must be made available to former employees or their designated representatives. Section 8(c)(3) of the Act explicitly provides, "former employees to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents". Records are available to designated representatives to assure access to the information by the current or former employee where he is incapacitated, unable to inspect or understand the records, or simply desires that his representative inspect them. The Act recognizes the legitimate role of employee representatives in assuring occupational safety and health.

The standard is also clarified to provide that medical records be made available upon request for examination and copying to a physician or other individual designated by the affected current employee or former employee. The purpose of the requirement is to protect the current or former employee's health by providing physicians and individuals designated by employees access to medical records useful in the diagnosis of illness. Records are available to designated representatives for the reasons noted above.

One commenter questioned the fact that the standard enables OSHA and NIOSH to have access to medical records without specifying confidentiality or otherwise limiting circulation of the information (exhibit 4-8, p. 14). OSHA recognizes that a physician's records may contain a wide range of personal and medical information deemed to be confidential or private. For this reason, the standard limits the contents of the medical record to such information as is related to DBCP exposure. Indeed, the standard requires in paragraph (m)(5)(ii) that the employer advise the physician that the physician's opinion, which becomes a part of the medical record, should not reveal findings unrelated to occupational exposure. The need of OSHA and NIOSH to have access to this information has already been thoroughly discussed. The privacy rights of the individuals would be appropriately protected by the Privacy Act and implementing regulations.

To assure that the records will be preserved for the required retention period, the standard requires an employer, who ceases to do business, to transfer his records to his successor and, in the event that there is no successor, to transfer the records to the Director of NIOSH.

16. Paragraph (q)—*Observation of monitoring.* Section 8(c)(3) of the Act authorizes the Secretary to require that employers provide employees or their representatives with the opportunity to observe monitoring of employee exposure to toxic substances or harmful physical agents. In accordance with this section, the standard contains provisions for such observation of DBCP monitoring. To assure that the right to observe is meaningful, observers are entitled to receive an explanation of the measurement procedure, to observe all steps related to the measurement procedure, and record the results obtained.

The observer, whether an employee or designated representative, must be

provided with, and is required to use, any personal protective devices required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

17. Paragraph (r)—*Appendices.* The standard includes three appendices: Appendix A titled "Substance Safety Data Sheet", Appendix B titled "Substance Technical Guidelines", and Appendix C titled "Medical Surveillance Guidelines". It should be noted that appendices are for informational purposes only. None of the statements contained therein should be construed as imposing a mandatory requirement not otherwise in the standard or negating any requirement which is imposed by the standard.

The information in appendix A is specifically written for the employee. Appendix B contains additional scientific and technical information to aid the employer in complying with requirements of the standard. Appendix C gives the employer a means of providing the examining physician with an explanation of the potential health effects of exposure to DBCP and provides information needed by the physician to evaluate the results of the medical examination. Appendix C also lists other types of examinations, not required by the individual standard, which may help the physician in making an accurate determination of whether an employee should be exposed or should continue to be exposed to DBCP.

VI. Authority

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599, 29 U.S.C. 653, 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations, is hereby amended by revising § 1910.1044 to provide a permanent occupational safety and health standard for exposure to DBCP.

In order to ensure that affected employers and employees will be informed of the existence of the new provisions and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the new requirements, the effective date of the revision to § 1910.1044 will be April 17, 1978. To provide continued protection for employees until that date, the provisions currently contained in § 1910.1044 are promulgated pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act as an occupational safety and health standard effective March 17, 1978. The revision to § 1910.1044 will supersede these provisions as of April 10, 1978.

Signed at Washington, D.C., this 10th day of March 1978.

Eula Bingham,
Assistant Secretary of Labor.

§ 1910.1044 1,2-dibromo-3-chloropropane.

(a) *Scope and application.* (1) This section applies to occupational exposure to 1,2-dibromo-3-chloropropane (DBCP).

(2) This section does not apply to:

(i) Exposure to DBCP which results solely from the application and use of DBCP as a pesticide; or

(ii) The storage, transportation, distribution or sale of DBCP in intact containers sealed in such a manner as to prevent exposure to DBCP vapors or liquid, except for the requirements of paragraphs (i), (n) and (o) of this section.

(b) *Definitions.* "Authorized person" means any person required by his duties to be present in regulated areas and authorized to do so by his employer, by this section, or by the Act. "Authorized person" also includes any person entering such areas as a designated representative of employees exercising an opportunity to observe employee exposure monitoring.

"DBCP" means 1,2-dibromo-3-chloropropane, Chemical Abstracts Service Registry Number 96-12-8, and includes all forms of DBCP.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment which may, or does, result in an unexpected release of DBCP.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

(c) *Permissible exposure limit.*—(1) *Inhalation.* The employer shall assure that no employee is exposed to an airborne concentration of DBCP in excess of 1 part DBCP per billion parts of air (ppb) as an 8-hour time-weighted average.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to eye or skin contact with DBCP.

(d) *Notification of use.* Within ten (10) days following the introduction of DBCP into the workplace, every employer who has a workplace where DBCP is present, shall report the following information to the nearest OSHA Area Office for each such workplace;

(1) The address and location of the workplace:

(2) A brief description of each process or operation which may result in employee exposure to DBCP;

(3) The number of employees engaged in each process or operation who may be exposed to DBCP and an estimate of the frequency and degree of exposure that occurs; and

(4) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to DBCP.

(e) *Regulated areas.* (1) The employer shall establish, within each place of employment, regulated areas wherever DBCP concentrations are in excess of the permissible exposure limit.

(2) The employer shall limit access to regulated areas to authorized persons.

(f) *Exposure monitoring.*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to DBCP over an 8-hour period.

(ii) For the purposes of this paragraph, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial.* Each employer who has a place of employment in which DBCP is present, shall monitor each workplace and work operation to accurately determine the airborne concentrations of DBCP to which employees may be exposed.

(3) *Frequency.* (i) If the monitoring required by this section reveals employee exposures to be below the permissible exposure limit, the employer shall repeat these measurements at least quarterly.

(ii) If the monitoring required by this section reveals employee exposures to be in excess of the permissible exposure limit, the employer shall repeat these measurements for each such employee at least monthly. The employer shall continue monthly monitoring until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limit. Thereafter the employer shall monitor at least quarterly.

(4) *Additional.* Whenever there has been a production, process, control, or personnel change which may result in any new or additional exposure to DBCP, or whenever the employer has any reason to suspect new or additional exposures to DBCP, the employer shall monitor the employees potentially affected by such change for the

purpose of redetermining their exposure.

(5) *Employee notification.* (i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of the measurements which represent the employee's exposure.

(ii) Whenever the results indicate that employee exposure exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limit.

(6) *Accuracy of measurement.* The employer shall use a method of measurement which has an accuracy, to a confidence level of 95 percent, of not less than plus or minus 25 percent for concentrations of DBCP at or above the permissible exposure limit.

(g) *Methods of compliance.*—(1) *Priority of compliance methods.* The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to DBCP at or below the permissible exposure limit, except to the extent that the employer establishes that such controls are not feasible. Where feasible engineering and work practice controls are not sufficient to reduce employee exposures to within the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls, and shall supplement them by use of respiratory protection.

(2) *Compliance program.* The employer shall establish and implement a written program to reduce employee exposures to DBCP to or below the permissible exposure limit solely by means of engineering and work practice controls as required by paragraph (g)(1) of this section.

(ii) The written program shall include a detailed schedule for development and implementation of the engineering and work practice controls. These plans shall be revised at least every six months to reflect the current status of the program.

(iii) Written plans for these compliance programs shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative of employees.

(iv) The employer shall institute and maintain at least the controls described in his most recent written compliance program.

(h) *Respirators.*—(1) *General.* Where respiratory protection is required under this section, the employer shall select, provide and assure the proper use of respirators. Respirators shall be used in the following circumstances:

(i) During the period necessary to install or implement feasible engineering and work practice controls; or

(ii) During maintenance and repair activities in which engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limit; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

TABLE 1.—*Respiratory protection for DBCP*

Airborne concentration of DBCP or condition of use	Respirator type
(a) Less than or equal to 10 ppb.	(1) Any supplied-air respirator; or (2) any self-contained breathing apparatus.
(b) Less than or equal to 50 ppb.	(1) Any supplied-air respirator with full facepiece, helmet, or hood; or (2) any self-contained breathing apparatus with full facepiece.
(c) Less than or equal to 1,000 ppb.	(1) A Type C supplied-air respirator operated in pressure-demand or other positive pressure or continuous flow mode.
(d) Less than or equal to 2,000 ppb.	(1) A Type C supplied-air respirator with full facepiece operated in pressure-demand or other positive pressure mode, or with full facepiece, helmet, or hood operated in continuous flow mode.
(e) Greater than 2,000 ppb or entry and escape from unknown concentrations.	(1) A combination respirator which includes a Type C supplied-air respirator with full facepiece operated in pressure-demand or other positive pressure or continuous flow mode and an auxiliary self-contained breathing apparatus operated in pressure-demand or positive pressure mode; or (2) a self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode.
(f) Firefighting.....	(1) A self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their faces and respirator facepieces as needed to prevent potential skin irritation associated with respirator use.

(i) *Emergency situations.*—(1) *Written plans.* (i) A written plan for emergency situations shall be developed for each workplace in which DBCP is present.

(ii) Appropriate portions of the plan shall be implemented in the event of an emergency.

(2) Employees engaged in correcting emergency conditions shall be equipped as required in paragraphs (h) and (j) of this section until the emergency is abated.

(3) *Evacuation.* Employees not engaged in correcting the emergency shall be removed and restricted from the area and normal operations in the affected area shall not be resumed until the emergency is abated.

(4) *Alerting employees.* Where there is a possibility of employee exposure to DBCP due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(5) *Medical surveillance.* For any employee exposed to DBCP in an emergency situation, the employer shall provide medical surveillance in accordance with paragraph (m) (6) of this section.

(6) *Exposure monitoring.* (i) Following an emergency, the employer shall conduct monitoring which complies with paragraph (f) of this section.

(ii) In workplaces not normally subject to periodic monitoring, the employer may terminate monitoring when two consecutive measurements indicate exposures below the permissible exposure limit.

(j) *Protective clothing and equipments.*—(1) *Provision and use.* Where there is any possibility of eye or dermal contact with liquid or solid DBCP, the employer shall provide, at no cost to the employee, and assure that the employee wears impermeable protective clothing and equipment to protect the area of the body which may come in contact with DBCP. Eye and face protection shall meet the requirements of § 1910.133 of this Part.

(2) *Removal and storage.* (i) The employer shall assure that employees remove DBCP contaminated work clothing only in change rooms provided in accordance with paragraph (l) (1) of this section.

(ii) The employer shall assure that employees promptly remove any protective clothing and equipment which becomes contaminated with DBCP-containing liquids and solids. This clothing shall not be reworn until the

DBCP has been removed from the clothing or equipment.

(iii) The employer shall assure that no employee takes DBCP contaminated protective devices and work clothing out of the change room, except those employees authorized to do so for the purpose of laundering, maintenance, of disposal.

(iv) DBCP-contaminated protective devices and work clothing shall be placed and stored in closed containers which prevent dispersion of the DBCP outside the container.

(v) Containers of DBCP contaminated protective devices or work clothing which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal, shall bear labels in accordance with paragraph (o)(3) of this section.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair, or replace protective clothing and equipment required by this paragraph to maintain their effectiveness. The employer shall provide clean protective clothing and equipment at least daily to each affected employee.

(ii) The employer shall inform any person who launders or clean DBCP-contaminated protective clothing or equipment of the potentially harmful effects of exposure to DBCP.

(iii) The employer shall prohibit the removal of DBCP from protective clothing and equipment by blowing or shaking.

(k) *Housekeeping.*—(1) *Surfaces.* (i) All workplace surfaces shall be maintained free of visible accumulations of DBCP.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces is prohibited where DBCP dusts or liquids are present.

(iii) Where vacuuming methods are selected to clean floors and other surfaces, either portable units or a permanent system may be used.

(*a*) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that DBCP is not reintroduced into the workplace air; and

(*b*) Portable vacuum units used to collect DBCP may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (o)(3) of this section.

(iv) Cleaning of floors and other surfaces contaminated with DBCP-containing dusts shall not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) *Liquids.* Where DBCP is present in a liquid form, or as a resultant vapor, all containers or vessels containing DBCP shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) *Waste disposal.* DBCP waste scrap, debris, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of DBCP outside the container.

(l) *Hygiene facilities and practices.*—(1) *Change rooms.* The employer shall provide clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment whenever employees are required to wear protective clothing and equipment in accordance with paragraphs (h) and (j) of this section.

(2) *Showers.* (i) The employer shall assure that employees working in the regulated area shower at the end of the work shift.

(ii) The employer shall assure that employees whose skin becomes contaminated with DBCP-containing liquids or solids immediately wash or shower to remove any DBCP from the skin.

(iii) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(3) *Lunchrooms.* The employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in regulated areas.

(4) *Lavatories.* (i) The employer shall assure that employees working in the regulated area remove protective clothing and wash their hands and face prior to eating.

(ii) The employer shall provide a sufficient number of lavatory facilities which comply with 29 CFR 1910.141(d) (1) and (2).

(5) *Prohibition of activities in regulated areas.* The employer shall assure that, in regulated areas, food or beverages are not present or consumed, smoking products and implements are not present or used, and cosmetics are not present or applied.

(m) *Medical surveillance.*—(1) *General.* (i) The employer shall make available a medical surveillance program for employees who work in regulated areas and employees who are subjected to DBCP exposures in an emergency situation.

(ii) All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) *Frequency and content.* At the time of initial assignment, and annually thereafter, the employer shall provide a medical examination for employees who work in regulated areas, which includes at least the following:

(i) A medical and occupational history including reproductive history.

(ii) A physical examination, including examination of the genito-urinary tract, testicle size and body habitus, including a determination of sperm count.

(iii) A serum specimen shall be obtained and the following determinations made by radioimmunoassay techniques utilizing National Institutes of Health (NIH) specific antigen or one of equivalent sensitivity:

(*a*) Serum follicle stimulating hormone (FSH);

(*b*) Serum luteinizing hormone (LH); and

(*c*) Serum total estrogen (females).

(iv) Any other tests deemed appropriate by the examining physician.

(3) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to DBCP, the employer shall provide the employee with a medical examination which shall include those elements considered appropriate by the examining physician.

(4) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this regulation and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The level of DBCP to which the employee is exposed; and

(iv) A description of any personal protective equipment used or to be used.

(5) *Physician's written opinion.* (i) For each examination under this section, the employer shall obtain and provide the employee with a written opinion from the examining physician which shall include:

(*a*) The results of the medical tests performed;

(*b*) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of health from exposure to DBCP; and

(*c*) Any recommended limitations upon the employee's exposure to DBCP or upon the use of protective clothing and equipment such as respirators.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure.

(6) *Emergency situations.* If the employee is exposed to DBCP in an emergency situation, the employer shall provide the employee with a sperm count test as soon as practicable, or, if the employee has been vasectionized or is unable to produce a semen specimen, the hormone tests contained in paragraph (m)(2)(iii) of this section. The employer shall provide these same tests three months later.

(n) *Employee information and training.*—(1) *Training program.* (i) The

employer shall institute a training program for all employees who may be exposed to DBCP and shall assure their participation in such training program.

(ii) The employer shall assure that each employee is informed of the following:

(*a*) The information contained in Appendix A;

(*b*) The quantity, location, manner of use, release or storage of DBCP and the specific nature of operations which could result in exposure to DBCP as well as any necessary protective steps;

(*c*) The purpose, proper use, and limitations of respirators;

(*d*) The purpose and description of the medical surveillance program required by paragraph (m) of this section; and

(*e*) A review of this standard, including appendices.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(o) *Signs and labels.*—(1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all regulated areas. These signs shall bear the legend:

DANGER

1,2-Dibromo-3-chloropropane

(*Insert appropriate trade or common names*)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

RESPIRATOR REQUIRED

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of DBCP and of products containing DBCP in the workplace, and that the labels remain affixed when the DBCP or products containing DBCP are sold, distributed, or otherwise leave the employer's workplace. Where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph need not be affixed.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

1,2-Dibromo-3-chloropropane

CANCER HAZARD

(p) *Recordkeeping.*—(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (f) of this section.

(ii) This record shall include:

(*a*) The dates, number, duration and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(*b*) A description of the sampling and analytical methods used;

(*c*) Type of respiratory protective devices worn, if any; and

(*d*) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (m) of this section.

(ii) This record shall include:

(*a*) The name and social security number of the employee;

(*b*) A copy of the physician's written opinion;

(*c*) Any employee medical complaints related to exposure to DBCP;

(*d*) A copy of the information provided the physician as required by paragraphs (m)(4)(ii) through (m)(4)(iv) of this section; and

(*e*) A copy of the employee's medical and work history.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that all employee exposure monitoring records required by this section be made available for examination and copying to affected employees or their designated representatives.

(iii) The employer shall assure that former employees and former employee's designated representatives have access to such records as will indicate the former employee's own exposure to DBCP.

(iv) The employer shall assure that employee medical records required to be maintained by this section be made available, upon request, for examination and copying to the employee or former employee and to a physician or other individual designated by the affected employee or former employee.

(4) *Transfer of records.* (i) If the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (p) of this section for the prescribed period.

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall transmit these records by mail to the Director.

(iii) At the expiration of the retention period for the records required to be maintained under paragraph (p) of this section, the employer shall transmit these records by mail to the Director.

(q) *Observation of monitoring*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, with an opportunity to observe any monitoring of employee exposure to DBCP required by this section.

(2) *Observation procedures.* (i) Whenever observation of the measuring or monitoring of employee exposure to DBCP requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring or measurement, observers shall be entitled to:

(*a*) Receive an explanation of the measurement procedures;

(*b*) Observe all steps related to the measurement of airborne concentrations of DBCP performed at the place of exposure; and

(*c*) Record the results obtained.

(r) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

APPENDIX A—SUBSTANCE SAFETY DATA SHEET FOR DBCP

I. SUBSTANCE IDENTIFICATION

A. Synonyms and trades names: DBCP; Dibromochloropropane; Fumazone (Dow Chemical Company TM); Nemafume; Nemagon (Shell Chemical Co. TM); Nemaset; BBC 12; and OS 1879.

B. Permissible exposure:

1. *Airborne.* 1 part DBCP vapor per billion parts of air (1 ppb); time-weighted average (TWA) for an 8-hour workday.

2. *Dermal.* Eye contact and skin contact with DBCP are prohibited.

C. Appearance and odor: Technical grade DBCP is a dense yellow or amber liquid with a pungent odor. It may also appear in granular form, or blended in varying concentrations with other liquids.

D. Uses: DBCP is used to control nematodes, very small worm-like plant parasites, on crops including cotton, soybeans, fruits, nuts, vegetables and ornamentals.

II. HEALTH HAZARD DATA

A. Routes of entry: Employees may be exposed:

1. Through inhalation (breathing);
2. Through ingestion (swallowing);
3. Skin contact; and
4. Eye contact.

B. Effects of exposure:

1. *Acute exposure.* DBCP may cause drowsiness, irritation of the eyes, nose, throat and skin, nausea and vomiting. In addition, overexposure may cause damage to the lungs, liver or kidneys.

2. *Chronic exposure.* Prolonged or repeated exposure to DBCP has been shown to cause sterility in humans. It also has been shown to produce cancer and sterility in laboratory animals and has been determined to constitute an increased risk of cancer in man.

3. *Reporting Signs and Symptoms.* If you develop any of the above signs or symptoms that you think are caused by exposure to DBCP, you should inform your employer.

III. EMERGENCY FIRST AID PROCEDURES

A. *Eye exposure.* If DBCP liquid or dust containing DBCP gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with DBCP.

B. *Skin exposure.* If DBCP liquids or dusts containing DBCP get on your skin, immediately wash using soap or mild detergent and water. If DBCP liquids or dusts containing DBCP penetrate through your clothing, remove the clothing immediately and wash. If irritation is present after washing get medical attention.

C. *Breathing.* If you or any person breathe in large amounts of DBCP, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Do not use mouth-to-mouth. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. *Swallowing.* When DBCP has been swallowed and the person is conscious, give the person large amounts of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. *Rescue.* Notify someone. Put into effect the established emergency rescue procedures. Know the locations of the emergency rescue equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. *Respirators.* You may be required to wear a respirator in emergencies and while your employer is in the process of reducing DBCP exposures through engineering controls. If respirators are worn, they must have a National Institute for Occupational Safety and Health (NIOSH) approval label (Older respirators may have a Bureau of Mines Approval label). For effective protection, a respirator must fit your face and head snugly. The respirator should not be loosened or removed in work situations where its use is required. DBCP does not have a detectable odor except at 1,000 times or more above the permissible exposure limit. If you can smell DBCP while wearing a respirator, the respirator is not working correctly; go immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. *Protective clothing.* When working with DBCP you must wear for your protection impermeable work clothing provided by your employer. (Standard rubber and neoprene protective clothing do not offer adequate protection).

DBCP must never be allowed to remain on the skin. Clothing and shoes must not be allowed to become contaminated with DBCP, and if they do, they must be promptly removed and not worn again until completely free of DBCP. Turn in impermeable clothing that has developed leaks for repair or replacement.

C. *Eye protection.* You must wear splashproof safety goggles where there is any possibility of DBCP liquid or dust contacting your eyes.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. DBCP must be stored in tightly closed containers in a cool, well-ventilated area.

B. If your work clothing may have become contaminated with DBCP, or liquids or dusts containing DBCP, you must change into uncontaminated clothing before leaving the work premises.

C. You must promptly remove any protective clothing that becomes contaminated with DBCP. This clothing must not be reworn until the DBCP is removed from the clothing.

D. If your skin becomes contaminated with DBCP, you must immediately and thoroughly wash or shower with soap or mild detergent and water to remove any DBCP from your skin.

E. You must not keep food, beverages, cosmetics, or smoking materials, nor eat or smoke, in regulated areas.

F. If you work in a regulated area, you must wash your hands thoroughly with soap or mild detergent and water, before eating, smoking or using toilet facilities.

G. If you work in a regulated area, you must remove any protective equipment or clothing before leaving the regulated area.

H. Ask your supervisor where DBCP is used in your work area and for any additional safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for DBCP. In addition, your employer must instruct you in the safe use of DBCP, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to DBCP. You or your representative have the right to observe employee exposure measurements and to record the result obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he is required to inform you of the actions which are being taken to reduce your exposure.

C. Your employer is required to keep records of your exposure and medical examinations. Your employer is required to keep exposure and medical data for at least 40 years or the duration of your employment plus 20 years, whichever is longer.

D. Your employer is required to release exposure and medical records to you, your physician, or other individual designated by you upon your written request.

APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES FOR DBCP

I. PHYSICAL AND CHEMICAL DATA

A. Substance Identification

1. Synonyms: 1,2-dibromo-3-chloropropane; DBCP, Fumazone; Nemafume; Nemagon; Nemaset; BBC 12; OS 1879. DBCP is also included in agricultural pesticides and fumigants which include the phrase "Nema———" in their name.
2. Formula: C3H5Br2 C1.
3. Molecular Weight: 236.

B. Physical Data:

1. Boiling point (760 mm HG): 195C (383F)
2. Specific gravity (water=1): 2.093.
3. Vapor density (air=1 at boiling point of DBCP): Data not available.
4. Melting point: 6C (43F).
5. Vapor pressure at 20C (68F): 0.8 mm Hg
6. Solubility in water: 1000 ppm.
7. Evaporation rate (Butyl Acetate=1): very much less than 1.
8. Appearance and odor: Dense yellow or amber liquid with a pungent odor at high concentrations. Any detectable odor of DBCP indicates overexposure.

II. FIRE EXPLOSION AND REACTIVITY HAZARD DATA

A. Fire

1. Flash point: 170F (77C)
2. Autoignition temperature: Data not available.
3. Flammable limits in air, percent by volume: Data not available.
4. Extinguishing media: Carbon dioxide, dry chemical.
5. Special fire-fighting procedures: Do not use a solid stream of water since a stream will scatter and spread the fire. Use water spray to cool containers exposed to a fire.
6. Unusual fire and explosion hazards: None known.
7. For purposes of complying with the requirements of § 1910.106, liquid DBCP is classified as a Class III A combustible liquid.
8. For the purpose of complying with § 1910.309, the classification of hazardous locations as described in article 500 of the National Electrical Code for DBCP shall be Class I, Group D.
9. For the purpose of compliance with § 1910.157, DBCP is classified as a Class B fire hazard.
10. For the purpose of compliance with § 1910.178, locations classified as hazardous locations due to the presence of DBCP shall be Class I, Group D.
11. Sources of ignition are prohibited where DBCP presents a fire or explosion hazard.

B. Reactivity

1. Conditions contributing to instability: None known.
2. Incompatibilities: Reacts with chemically active metals, such as aluminum, magnesium and tin alloys.
3. Hazardous decomposition products: Toxic gases and vapors (such as HBr, HCl and carbon monoxide) may be released in a fire involving DBCP.
4. Special precautions: DBCP will attack some rubber materials and coatings.

III. SPILL, LEAK AND DISPOSAL PROCEDURES

A. If DBCP is spilled or leaked, the following steps should be taken:

1. The area should be evacuated at once and re-entered only after thorough ventilation.

2. Ventilate area of spill or leak.

3. If in liquid form, collect for reclamation or absorb in paper, vermiculite, dry sand, earth or similar material.

4. If in solid form, collect spilled material in the most convenient and safe manner for reclamation or for disposal.

B. Persons not wearing protective equipment must be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste Disposal Methods:

1. For small quantities of liquid DBCP, absorb on paper towels, remove to a safe place (such as a fume hood) and burn the paper. Large quantities can be reclaimed or collected and atomized in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. If liquid DBCP is absorbed in vermiculite, dry sand, earth or similar material and placed in sealed containers it may be disposed of in a State-approved sanitary landfill.

2. If in solid form, for small quantities, place on paper towels, remove to a safe place (such as a fume hood) and burn. Large quantities may be reclaimed. However, if this is not practical, dissolve in a flammable solvent (such as alcohol) and atomize in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. DBCP in solid form may also be disposed in a state-approved sanitary landfill.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the permissible exposure limit.

1. *Eight Hour Exposure Evaluation:* Measurements taken for the purpose of determining employee exposure under this section are best taken so that the average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. *Monitoring Techniques:* The sampling and analysis under this section may be performed by collecting the DBCP vapor on petroleum based charcoal absorption tubes with subsequent chemical analyses. The method of measurement chosen should determine the concentration of airborne DBCP at the permissible exposure limit to an accuracy of plus or minus 25 percent. If charcoal tubes are used, a total volume of 10 liters should be collected at a flow rate of 50 cc. per minute for each tube. Analyze the resultant samples as you would samples of halogenated solvent.

B. Since many of the duties relating to employee protection are dependent on the results of monitoring and measuring procedures, employers should assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. PROTECTIVE CLOTHING

Employees should be required to wear appropriate protective clothing to prevent any possibility of skin contact with DBCP. Because DBCP is absorbed through the skin, it is important to prevent skin contact with both liquid and solid forms of DBCP. Protective clothing should include impermeable coveralls or similar fullbody work clothing, gloves, headcoverings, and workshoes or shoe coverings. Standard rubber and neoprene gloves do not offer adequate protection and should not be relied upon to keep DBCP off the skin. DBCP should never be allowed to remain on the skin. Clothing and shoes should not be allowed to become contaminated with the material, and if they do, they should be promptly removed and not worn again until completely free of the material. Any protective clothing which has developed leaks or is otherwise found to be defective should be repaired or replaced. Employees should also be required to wear splash-proof safety goggles where there is any possibility of DBCP contacting the eyes.

VI. HOUSEKEEPING AND HYGIENE FACILITIES

1. The workplace must be kept clean, orderly and in a sanitary condition;

2. Dry sweeping and the use of compressed air is unsafe for the cleaning of floors and other surfaces where DBCP dust or liquids are found. To minimize the contamination of air with dust, vacuuming with either portable or permanent systems must be used. If a portable unit is selected, the exhaust must be attached to the general workplace exhaust ventilation system, or collected within the vacuum unit equipped with high efficiency filters or other appropriate means of contamination removal and not used for other purposes. Units used to collect DBCP must be labeled.

3. Adequate washing facilities with hot and cold water must be provided, and maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of DBCP from the skin.

4. Change or dressing rooms with individual clothes storage facilities must be provided to prevent the contamination of street clothes with DBCP. Because of the hazardous nature of DBCP, contaminated protective clothing must be stored in closed containers for cleaning or disposal.

VII. MISCELLANEOUS PRECAUTIONS

A. Store DBCP in tightly closed containers in a cool, well ventilated area.

B. Use of supplied-air suits or other impervious clothing (such as acid suits) may be necessary to prevent skin contact with DBCP. Supplied-air suits should be selected, used, and maintained under the supervision of persons knowlegeable in the limitations and potential life-endangering characteristics of supplied-air suits.

C. The use of air-conditioned suits may be necessary in warmer climates.

D. Advise employees of all areas and operations where exposure to DBCP could occur.

VIII. COMMON OPERATIONS

Common operations in which exposure to DBCP is likely to occur are: during its production; and during its formulation into pesticides and fumigants.

APPENDIX C.—MEDICAL SURVEILLANCE GUIDELINES FOR DBCP

I. ROUTE OF ENTRY

Inhalation; skin absorption

II. TOXICOLOGY

Recent data collected on workers involved in the manufacture and formulation of DBCP has shown that DBCP can cause sterility at very low levels of exposure. This finding is supported by studies showing that DBCP causes sterility in animals. Chronic exposure to DBCP resulted in pronounced necrotic action on the parenchymatous organs (i.e., liver, kidney, spleen) and on the testicles of rats at concentrations as low as 5 ppm. Rats that were chronically exposed to DBCP also showed changes in the composition of the blood, showing low RBC, hemoglobin, and WBC, and high reticulocyte levels as well as functional hepatic disturbance, manifesting itself in a long prothrombin time. Reznik et al. noted a single dose of 100 mg produced profound depression of the nervous system of rats. Their condition gradually improved. Acute exposure also resulted in the destruction of the sex gland activity of male rats as well as causing changes in the estrous cycle in female rats. Animal studies have also associated DBCP with an increased incidence of carcinoma. Olson, et al. orally administered DBCP to rats and mice 5 times per week at experimentally predetermined maximally tolerated doses and at half those doses. As early as ten weeks after initiation of treatment, DBCP induced a high incidence of squamous cell carcinomas of the stomach with metastases in both species. DBCP also induced mammary adenocarcinomas in the female rats at both dose levels.

III. SIGNS AND SYMPTOMS

A. Inhalation: Nausea, eye irritation, conjunctivitis, respiratory irritation, pulmonary congestion or edema, CNS depression with apathy, sluggishness, and ataxia.

B. Dermal: Erythema or inflammation and dermatitis on repeated exposure.

IV. SPECIAL TESTS

A. *Semen analysis:* The following information excerpted from the document "Evaluation of Testicular Function", submitted by the Corporate Medical Department of the Shell Oil Company (exhibit 39-3), may be useful to physicians conducting the medical surveillance program;

In performing semen analyses certain minimal but specific criteria should be met:

1. It is recommended that a minimum of three valid semen analyses be obtained in order to make a determination of an individual's average sperm count.

2. A period of sexual abstinence is necessary prior to the collection of each masturbatory sample. It is recommended that intercourse or masturbation be performed 48 hours before the actual specimen collection. A period of 48 hours of abstinence would follow; then the masturbatory sample would be collected.

3. Each semen specimen should be collected in a clean, widemouthed, glass jar (not necessarily pre-sterilized) in a manner designated by the examining physician. Any part of the seminal fluid exam should be initialed *only after liquifaction* is complete, i.e., 30 to 45 minutes after collection.

4. Semen volume should be measured to the nearest $\frac{1}{10}$ of a cubic centimeter.

5. Sperm density should be determined using routine techniques involving the use of a white cell pipette and a hemocytometer chamber. The immobilizing fluid most effective and most easily obtained for this process is distilled water.

6. Thin, dry smears of the semen should be made for a morphologic classification of the sperm forms and should be stained with either hematoxalin or the more difficult, yet more precise, Papanicolaou technique.

Also of importance to record is obvious sperm agglutination, pyospermia, delayed liquifaction (greater than 30 minutes), and hyperviscosity. In addition, pH, using nitrazine paper, should be determined.

7. A total morphology evaluation should include percentages of the following:

a. Normal (oval) forms,

b. Tapered forms,

c. Amorphous forms (include large and small sperm shapes),

d. Duplicated (either heads or tails) forms, and

e. Immature forms.

8. Each sample should be evaluated for sperm *viability* (percent viable sperm moving at the time of examination) as well as sperm *motility* (subjective characterization of "purposeful forward sperm progression" of the majority of those viable sperm analyzed) within two hours after collection, ideally by the same or equally qualified examiner.

B. *Serum determinations:* The following serum determinations should be performed by radioimmuno-assay techniques using National Institutes of Health (NIH) specific antigen or antigen preparations of equivalent sensitivity:

1. Serum follicle stimulating hormone (FSH);

2. Serum luteinizing hormone (LH); and

3. Serum total estrogen (females only).

V. TREATMENT

Remove from exposure immediately, give oxygen or artificial resuscitation if indicated. Contaminated clothing and shoes should be removed immediately. Flush eyes and wash contaminated skin. If swallowed and the person is conscious, induce vomiting. Recovery from mild exposures is usually rapid and complete.

VI. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. *Other considerations.* DBCP can cause both acute and chronic effects. It is important that the physician become familiar with the operating conditions in which exposure to DBCP occurs. Those with respiratory disorders may not tolerate the wearing of negative pressure respirators.

B. *Surveillance and screening.* Medical histories and laboratory examinations are required for each employee subject to exposure to DBCP. The employer should screen employees for history of certain medical conditions (listed below) which might place the employee at increased risk from exposure.

1. *Liver disease.* The primary site of biotransformation and detoxification of DBCP is the liver. Liver dysfunctions likely to inhibit the conjugation reactions will tend to promote the toxic actions of DBCP. These precautions should be considered before exposing persons with impaired liver function to DBCP.

2. *Renal disease.* Because DBCP has been associated with injury to the kidney it is important that special consideration be given to those with possible impairment of renal function.

3. *Skin desease.* DBCP can penetrate the skin and can cause erythema on prolonged exposure. Persons with pre-existing skin disorders may be more susceptible to the effects of DBCP.

4. *Blood dyscrasias.* DBCP has been shown to decrease the content of erythrocytes, hemoglobin, and leukocytes in the blood, as well as increase the prothrombin time. Persons with existing blood disorders may be more susceptible to the effects of DBCP.

5. *Reproductive disorders.* Animal studies have associated DBCP with various effects on the reproductive organs. Among these effects are atrophy of the testicles and changes in the estrous cycle. Persons with pre-existing reproductive disorders may be at increased risk to these effects of DBCP.

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